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No.

# In the Supreme Court of the United States

NATIONAL CORN GROWERS ASSOCIATION, ET AL.,
*Petitioners*,

v.

U.S. ENVIRONMENTAL PROTECTION AGENCY, ET AL.,
*Respondents*.

ON PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

## PETITION FOR A WRIT OF CERTIORARI

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## QUESTION PRESENTED

For nearly forty years, the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. § 346a(g)(2)(B), has required the Environmental Protection Agency (EPA) to hold a public evidentiary hearing before taking certain major agency actions, when a party objects to the proposed action and satisfies what the agency itself has described as "summary judgment-type procedures" that, among other things, require a hearing to resolve "disputed material factual issues." 74 Fed. Reg. 59,608, 59,623 (Nov. 18, 2009); *see* 40 C.F.R. § 178.32(b). During that time, EPA has never held such a hearing.

In this case, EPA refused to hold such a hearing before revoking the tolerances for—and thus effectively banning—a pesticide that has been used safely for decades, even though petitioners filed timely objections supported by ample expert data and other evidence calling into serious question the agency's findings on several material issues of fact. The District of Columbia Circuit upheld EPA's decision, holding that review of such a denial is highly deferential, that—paradoxically—the existence of an expert dispute over a critical factual issue was "fatal" to petitioners' request for a hearing, and that the agency properly refused to consider various objections based on "Catch-22" timing considerations. App.7a-13a.

If a hearing is not required under the FFDCA in this type of case, then as a practical matter the Act's hearing requirement is illusory. The question presented is whether the District of Columbia Circuit—in conflict with the decisions of this Court and other circuits, as well as with the agency's own regulations—has properly construed the FFDCA's hearing requirement and related rules.

## LIST OF PARTIES AND RULE 29.6 STATEMENT

Petitioners are the National Corn Growers Association, National Sunflower Association, National Potato Council, and FMC Corporation.

The National Corn Growers Association is a non-publicly held, not-for-profit 501(c)(5) corporation organized and existing under the laws of the State of Iowa. The National Corn Growers Association does not have a parent corporation. There is no publicly held corporation owning 10% or more of the National Corn Growers Association.

The National Sunflower Association is a non-profit commodity organization existing under the laws of the State of North Dakota. The National Sunflower Association does not have a parent corporation. There is no publicly held corporation owning 10% or more of the National Sunflower Association.

The National Potato Council is a non-publicly held 501(c)(5) not-for-profit corporation organized and existing under the laws of the State of Colorado. The National Potato Council does not have a parent corporation. There is no publicly held corporation owning 10% or more of the National Potato Council.

FMC Corporation is a publicly-traded corporation that has no parent organization. No publicly-held entity owns more than 10% of FMC Corporation.

Respondents are the U.S. Environmental Protection Agency (EPA) and Lisa P. Jackson, the Administrator of EPA.

## TABLE OF CONTENTS

Page

QUESTION PRESENTED ..... i

LIST OF PARTIES AND RULE 29.6 STATEMENT ..... ii

TABLE OF AUTHORITIES ..... vii

OPINIONS AND ORDERS BELOW ..... 1

JURISDICTION ..... 1

CONSTITUTIONAL, STATUTORY, AND REGULATORY PROVISIONS INVOLVED ..... 2

INTRODUCTION ..... 2

STATEMENT OF THE CASE ..... 5

A. Background ..... 5

B. Proceedings Below ..... 8

REASONS FOR GRANTING THE WRIT ..... 13

I. THE DISTRICT OF COLUMBIA CIRCUIT'S DECISION ON THE STANDARD FOR WHEN A HEARING IS REQUIRED UNDER THE FFDCA MERITS THIS COURT'S REVIEW ..... 14

A. The Decision Below Is Fundamentally Incompatible With Any "'Summary-Judgment Type' Standard" And Nullifies The FFDCA's Hearing Right ..... 15

B. The Decision Below Conflicts With This Court's Decision In *Weinberger* As Well As Decisions Of Other Circuits ..... 20

TABLE OF CONTENTS—Continued

Page

II. THE DISTRICT OF COLUMBIA CIRCUIT'S ENDORSEMENT OF EPA'S EXTRAORDINARY "CATCH-22" WAIVER RULE MERITS THIS COURT'S REVIEW ..... 26

A. EPA's "Catch-22" Waiver Standard Violates The FFDCA And The Agency's Own Regulations ..... 27

B. In This Respect Too, The Decision Below Conflicts With The Decisions Of This Court And Other Circuits ..... 29

III. THE QUESTION PRESENTED HAS FAR-REACHING SIGNIFICANCE AND IS UNDENIABLY IMPORTANT ..... 31

CONCLUSION ..... 35

APPENDIX TABLE OF CONTENTS

Opinion of the United States Court of Appeals for the District of Columbia Circuit, *National Corn Growers Ass'n v. EPA*, 613 F.3d 266 (D.C. Cir. 2010) ..... 1a

Carbofuran; Order Denying FMC's Objections and Requests for Hearing, 74 Fed. Reg. 59,608 (Nov. 18, 2009) (omitting "References" section) ..... 16a

Carbofuran; Final Tolerance Revocations, 74 Fed. Reg. 23,046 (May 15, 2009) (excerpts) ..... 343a

APPENDIX TABLE OF CONTENTS—Continued

Page

Carbofuran; Proposed Tolerance Revocations, 73 Fed. Reg. 44,864 (July 31, 2008) (excerpts) ..... 369a

Order Denying Motion for Stay, *National Corn Growers Ass'n v. EPA*, No. 09-1284 (D.C. Cir. Dec. 14, 2009) ..... 377a

Order Denying Rehearing, *National Corn Growers Ass'n v. EPA*, No. 09-1284 (D.C. Cir. Oct. 19, 2010) ..... 380a

Order Denying Rehearing En Banc, *National Corn Growers Ass'n v. EPA*, No. 09-1284 (D.C. Cir. Oct. 19, 2010) ..... 381a

21 U.S.C. § 346a (omitting footnotes) ..... 382a

40 C.F.R. § 178.20 ..... 429a

40 C.F.R. § 178.30 ..... 430a

40 C.F.R. § 178.32 ..... 432a

Comments in Opposition to Proposed Tolerance Revocations for Carbofuran, submitted by the National Potato Council, National Corn Growers Association, National Cotton Council, National Sunflower Association, and FMC Corporation (Sept. 29, 2008) (excerpts) ..... 434a

APPENDIX TABLE OF CONTENTS—Continued

Page

Objections to the Final Order Revoking Tolerances for Carbofuran, and Request for Public Evidentiary Hearing, with exhibits (June 30, 2009) (excerpts) ..... 440a

Exhibit 1 (excerpts) ..... 456a
Exhibit 2 (excerpts) ..... 464a
Exhibit 3 (excerpts) ..... 469a
Exhibit 13 excerpts) ..... 484a
Exhibit 15 (excerpts) ..... 491a
Exhibit 18 (excerpts) ..... 501a

# TABLE OF AUTHORITIES

Page(s)

## CASES

*Anderson v. Liberty Lobby, Inc.*,
477 U.S. 242 (1986) ..... 16, 17, 20

*Braxton v. United States*,
500 U.S. 344 (1991) ..... 26

*California v. Green*,
399 U.S. 149 (1970) ..... 3

*Citizens to Preserve Overton Park, Inc. v. Volpe*,
401 U.S. 402 (1971) ..... 18

*Crestview Parke Care Ctr. v. Thompson*,
373 F.3d 743 (6th Cir. 2004) ..... 25

*CropLife America v. EPA*,
329 F.3d 876 (D.C. Cir. 2003) ..... 5

*Department of Transportation v. Public Citizen*,
541 U.S. 752 (2004) ..... 30

*E.R. Squibb & Sons, Inc. v. Weinberger*,
483 F.2d 1382 (3d Cir. 1973) ..... 25, 26

*Forest Guardians v. United States Forest Service*,
495 F.3d 1162 (10th Cir. 2007) ..... 31

*Goldberg v. Kelly*,
397 U.S. 254 (1970) ..... 3

TABLE OF AUTHORITIES—Continued

Page(s)

*Greene v. McElroy*,
360 U.S. 474 (1959) ..... 3

*Hynson, Westcott & Dunning, Inc. v. Richardson*,
461 F.2d 215 (4th Cir. 1972) ..... 18, 23, 24

*'Ilio'Ulaokalani Coalition v. Rumsfeld*,
464 F.3d 1083 (9th Cir. 2006) ..... 31

*J.D. ex rel. J.D. v. Pawlet School District*,
224 F.3d 60 (2d Cir. 2000) ..... 25

*Jama v. Immigration & Customs Enforcement*,
543 U.S. 335 (2005) ..... 27

*Kleissler v. United States Forest Service*,
183 F.3d 196 (3d Cir. 1999) ..... 31

*Mountain Side Mobile Estates Partnership v. Secretary of HUD*,
56 F.3d 1243 (10th Cir. 1995) ..... 18

*Native Ecosystems Council v. Dombeck*,
304 F.3d 886 (9th Cir. 2002) ..... 30

*Pactra Industries, Inc. v. Consumer Products Safety Commission*,
555 F.2d 677 (1977) ..... 24, 26

*Phillips v. Cohen*,
400 F.3d 388 (6th Cir. 2005) ..... 16

TABLE OF AUTHORITIES—Continued

Page(s)

*Puerto Rico Aqueduct & Sewer Authority v. EPA*,
35 F.3d 600 (1st Cir. 1994), *cert. denied*, 513 U.S. 1148 (1995) ..... 22, 25

*Sims v. Apfel*,
530 U.S. 103 (2000) ..... 30

*Ramaprakash v. FAA*,
346 F.3d 1121 (D.C. Cir. 2003) ..... 19, 29

*Travers v. Shalala*,
20 F.3d 993 (9th Cir. 1994) ..... 25

*Trunk v. City of San Diego*,
Nos. 08-56415, 08-56436, 2011 U.S. App. LEXIS 53 (9th Cir. Jan. 4, 2011) ..... 16

*USV Pharmaceutical Corp. v. Secretary of Health, Education & Welfare*,
466 F.2d 455 (D.C. Cir. 1972) ..... 6

*United States v. Powell*,
423 U.S. 87 (1975) ..... 19

*Vermont Yankee Nuclear Power Corp. v. NRDC*,
435 U.S. 519 (1978) ..... 34

*Weinberger v. Hynson, Wescott & Dunning, Inc.*,
412 U.S. 609 (1973) ..... *passim*

## TABLE OF AUTHORITIES—Continued

Page(s)

### CONSTITUTIONAL PROVISIONS, STATUTES AND REGULATIONS

U.S. Const. amend. V, cl. 3 ..... 2

5 U.S.C. § 706(2) ..... 18

7 U.S.C. § 136 *et seq* ..... 5

21 U.S.C. § 346a(b)(2)(A)(ii) ..... 5

21 U.S.C. § 346a(d)(4)(A)(i) ..... 6

21 U.S.C. § 346a(g) ..... 2, 3, 6

21 U.S.C. § 346a(g)(2)(A) ..... 6, 11, 27

21 U.S.C. § 346a(g)(2)(B) ..... 6

28 U.S.C. § 1254(1) ..... 1

21 C.F.R. § 12.24 ..... 6

21 C.F.R. § 314.126 ..... 6

21 C.F.R. § 314.200 ..... 6

40 C.F.R. § 178.20(a) ..... 11, 27

40 C.F.R. § 178.32(b) ..... 6, 10

40 C.F.R. § 178.32(b)(2) ..... 22

TABLE OF AUTHORITIES—Continued

Page(s)

FEDERAL REGISTER

40 Fed. Reg. 22,950 (May 27, 1975) ..... 6

50 Fed. Reg. 41,938 (Oct. 16, 1985) ..... 7

53 Fed. Reg. 41,126 (Oct. 19, 1988) ..... 16

59 Fed. Reg. 33,684 (June 30, 1994) ..... 16

72 Fed. Reg. 39,318 (July 18, 2007) ..... 16

73 Fed. Reg. 42,683 (July 23, 2008) ..... 6, 16

73 Fed. Reg. 44,864 (July 31, 2008) ..... 8

74 Fed. Reg. 23,046 (May 15, 2009) ..... 9

74 Fed. Reg. 59,608 (Nov. 18, 2009) ..... 1

75 Fed. Reg. 55,997 (Sept. 15, 2010) ..... 13, 16, 29

OTHER AUTHORITY

Charles C. Ames & Steven C. McCracken, *Framing Regulatory Standards to Avoid Formal Adjudication: The FDA As a Case Study*, 64 Cal. L. Rev. 14 (1976) ..... 19

TABLE OF AUTHORITIES—Continued

Page(s)

Juliet Eilperin, *In Surprise Move, EPA Bans Carbofuran Residue on Food*, Washington Post, July 25, 2008 ..... 10

John M. Golden, *The Federal Circuit and the D.C. Circuit: Comparative Trials of Two Semi-Specialized Courts*, 78 Geo. Wash. L. Rev. 553 (2010) ..... 34

Richard A. Merrill & Michael Schewel, *FDA Regulation of Environmental Contaminants of Food*, 66 Va. L. Rev. 1357 (1980) ..... 6

Richard J. Pierce, Jr., *The Special Contributions of the D.C. Circuit to Administrative Law*, 90 Geo. L.J. 779 (2002) ..... 33

John G. Roberts, Jr., *What Makes the D.C. Circuit Different? A Historical View*, 92 Va. L. Rev. 375 (2006) ..... 33

Supreme Court Rule 10(a) ..... 26

Supreme Court Rule 10(c) ..... 26

## PETITION FOR A WRIT OF CERTIORARI

Petitioners, the National Corn Growers Association, *et al.*, respectfully petition for a writ of certiorari to review the judgment of the District of Columbia Circuit in this case.

## OPINIONS AND ORDERS BELOW

The District of Columbia Circuit's opinion (App.1a-15a) is reported at 613 F.3d 266. EPA's final order denying petitioners' objections and hearing requests is reported at 74 Fed. Reg. 59,608, and reproduced at App.16a-342a. EPA's final revocation order is reported at 74 Fed. Reg. 23,046, and excerpts of that order are reproduced at App.343a-68a. EPA's proposed revocation order is reported at 73 Fed. Reg. 44,864, and excerpts of that order are reproduced at App.369a-76a.

## JURISDICTION

The District of Columbia Circuit entered judgment on July 23, 2010, and denied timely petitions for rehearing and rehearing en banc on October 19, 2010. On December 23, 2010, the Chief Justice extended the time within which to file a petition for a writ of certiorari to and including February 16, 2011. This Court has jurisdiction under 28 U.S.C. § 1254(1).

## CONSTITUTIONAL, STATUTORY, AND REGULATORY PROVISIONS INVOLVED

The Due Process Clause of the Fifth Amendment to the Constitution provides in relevant part: "No person shall ... be deprived of life, liberty, or property, without due process of law ...." U.S. Const. amend. V, cl. 3.

Section 408(g) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. § 346a(g), states in relevant part:

> Within 60 days after a regulation or order is issued under subsection (d)(4), (e)(1)(A), (e)(1)(B), (f)(2), (n)(3), or (n)(5)(C), any person may file objections thereto with the Administrator, specifying with particularity the provisions of the regulation or order deemed objectionable and stating reasonable grounds therefor. ... An objection may include a request for a public evidentiary hearing upon the objection. The Administrator shall, upon the initiative of the Administrator or upon the request of an interested person and after due notice, hold a public evidentiary hearing if and to the extent the Administrator determines that such a public hearing is necessary to receive factual evidence relevant to material issues of fact raised by the objections.

Other relevant portions of the FFDCA and regulations of the U.S. Environmental Protection Agency (EPA) are set forth at App.382a-433a.

## INTRODUCTION

The ability to obtain a live hearing before a neutral factfinder to resolve material issues of disputed fact is a time-honored feature of our system of justice. As this

Court has observed, "[c]ertain principles," such as "confrontation and cross-examination," "have ancient roots" and "have remained relatively immutable in our jurisprudence." *Greene v. McElroy*, 360 U.S. 474, 496-97 & n.25 (1959). Indeed, a live hearing with cross-examination is the "greatest legal engine ever invented for the discovery of truth." *California v. Green*, 399 U.S. 149, 158 (1970) (quotation marks and citation omitted). For that reason, "'[t]his Court has been zealous to protect these rights from erosion. It has spoken out not only in criminal cases, but also in all types of cases where administrative actions were under scrutiny.'" *Goldberg v. Kelly*, 397 U.S. 254, 270 (1970) (quoting *Greene*, 360 U.S. at 497) (alterations omitted).

At issue here is Congress's requirement under the FFDCA that EPA must conduct a live hearing on revocation of pesticide "tolerances" (*i.e.*, limits of residues) when there are material issues of fact as to the safety of the pesticide and other factors. *See* 21 U.S.C. § 346a(g). By EPA's admission, the FFDCA imposes a "'summary-judgment type' standard" in deciding when a hearing is required. App.6a. But in the four decades that EPA has administered this hearing requirement—a provision that tracks similar hearing requirements for other agency actions—EPA has never conducted such a hearing. And in this case, the agency refused to conduct a hearing before banning a pesticide—carbofuran—that has been used safely for decades, notwithstanding the existence of several disputed issues of material fact and a prototypical battle of the experts going to the heart of the agency's determination that the product was unsafe.

In the decision below, the District of Columbia Circuit upheld EPA's refusal to hold a hearing,

adopting a standard for determining when a hearing is due under the FFDCA that effectively eviscerates the Act's hearing requirement. For example, even though the court recognized that the FFDCA and EPA's own regulations adopt "a 'summary-judgment type' standard" under which a hearing is required to resolve "material issue[s] of fact," App.6a, the court concluded that "a 'dispute between experts'" on a critical factual issue was "fatal" to petitioners' hearing request. App.13a. In addition, the court embraced a novel and far-reaching timing rule that gives EPA virtually free rein to reject evidence and arguments in support of hearing requests as either "too early" or "too late" under arbitrary, "Catch-22" timing considerations.

The District of Columbia Circuit's decision effectively eviscerates a critical statutory right and curtails the public's ability to challenge an agency's manipulation of disputed facts to reach a desired policy end. The decision conflicts not only with the agency's own regulations, but with decisions of this Court and other circuits. And the decision has far-reaching significance because the hearing requirement at issue is comparable to other hearing requirements governing administrative actions by EPA, the Food and Drug Administration (FDA), and the Consumer Products Safety Commission (CPSC) affecting a major segment of the nation's economy—including prescription drugs, medical devices, agriculture, food products and additives, and many other consumer products. As the most important circuit in the country for administrative law, the District of Columbia Circuit's ruling on the standard for obtaining a hearing under common administrative summary-judgment procedures is a matter of exceptional importance.

Certiorari is warranted to resolve the multifaceted conflicts of authority created by the decision below and to restore a critical statutory safeguard that Congress has granted the public on matters of enormous economic and public policy significance.

## STATEMENT OF THE CASE

### A. Background

#### 1. *Statutory and Regulatory Background*

Pesticides are regulated under both the FFDCA and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136 *et seq.* *See CropLife Am. v. EPA*, 329 F.3d 876, 879 (D.C. Cir. 2003). "FIFRA establishes a registration system allowing EPA to prescribe the conditions under which a pesticide may be sold or distributed." *Id.* Under FIFRA, EPA considers whether a pesticide "would cause 'unreasonable adverse effects on the environment,'" which includes "'unreasonable risk to man' or any 'human dietary risk.'" *Id.* (citation omitted). EPA also establishes "tolerance levels"—*i.e.*, "the amount of pesticide that may remain on food products"—under the FFDCA. *Id.* The FFDCA, in turn, "defines pesticide tolerances as 'safe' when there is 'a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue.'" *Id.* (quoting 21 U.S.C. § 346a(b)(2)(A)(ii)).

Under this scheme, the ability to sell a pesticide depends on the existence of a tolerance. EPA's ability to grant or revoke tolerances is circumscribed by a bifurcated rulemaking process: an initial informal rulemaking on a proposed and final order of revocation; and if contested, a second formal rulemaking that permits a party to object to the final order and request

an on-the-record hearing. 21 U.S.C. § 346a(g); *see* Richard A. Merrill & Michael Schewel, *FDA Regulation of Environmental Contaminants of Food*, 66 Va. L. Rev. 1357, 1382 (1980). The FFDCA provides that after EPA issues a "final regulation ... establishing, modifying, or revoking a tolerance," "any person may file objections thereto with the Administrator" and request "a public evidentiary hearing upon the objection." 21 U.S.C. § 346a(d)(4)(A)(i), (g)(2)(A), (g)(2)(B). The Act further states that EPA "shall, ... hold a public evidentiary hearing if and to the extent the Administrator determines that such a public hearing is necessary to receive factual evidence relevant to material issues of fact raised by the objections." *Id.* § 346a(g)(2)(B).

EPA's regulations governing such hearings (40 C.F.R. § 178.32(b)) create "summary judgment-type procedures" wherein a hearing will be granted upon request if petitioners raise material issues of fact. 73 Fed. Reg. 42,683, 42,694 (July 23, 2008); App.6a. EPA's "hearing request requirements are based heavily on FDA [hearing] regulations." App.82a; *see* 21 C.F.R. §§ 12.24, 314.126, 314.200. FDA's regulations, in turn, are "modeled after Rule 56 of the Federal Rules of Civil Procedure," *USV Pharm. Corp. v. Secretary of Health, Education & Welfare*, 466 F.2d 455, 461 (D.C. Cir. 1972), and reflect the guidance in this Court's decision in *Weinberger v. Hynson, Wescott & Dunning, Inc.*, 412 U.S. 609 (1973), which laid out several basic principles governing administrative summary judgment under the FFDCA. *See* 40 Fed. Reg. 22,950, 22,968 (May 27, 1975) (explaining that FDA's summary-judgment procedures "accurately reflect the legal standards enunciated by" *Weinberger*).

2. *Carbofuran And Its Uses*

This case involves the pesticide carbofuran, which since 1969 has been registered by EPA as meeting the human health and environmental safety requirements of FIFRA and the FFDCA. JA-162.[1] Carbofuran is a "cholinesterase inhibitor," which acts by inhibiting nervous system communication. JA-147, 166-67. When carbofuran is present below threshold levels, however, no adverse effects occur. *See* App.345a, 27a. In addition, the effects of carbofuran are rapidly reversible. JA-168. Recovery from carbofuran exposures begins within 15 to 40 minutes of exposure, with a half-life of approximately 2.5 hours and full recovery occurring within 24 hours. JA-621, JA-168. Because of the rapid recovery time, chronic exposures to carbofuran do not present a health risk. JA-168.

Carbofuran has been used safely for decades to control pest infestations in a variety of crops, including corn, sunflowers, pumpkins, and potatoes. *See generally* App.54a, 345a; JA-199-214. At its peak in the late 1980s, carbofuran was approved for use on 35 domestic crops and approximately 10-11 million pounds were applied annually. 50 Fed. Reg. 41,938, 41,941 (Oct. 16, 1985); App.344a-45a. With the emergence of new pesticides and other factors, carbofuran subsequently transitioned to a niche product for specific pest control problems. JA-361, 194-95. Current carbofuran usage (before EPA's ban took effect in December 2009) is about 200,000 pounds per year—a 98% reduction from peak levels. *See, e.g.*, App.501a-02a. There has never been a documented

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[1] "JA" refers to the joint appendix filed in this case in the United States Court of Appeals for the District of Columbia Circuit.

incident of any person suffering adverse health effects from dietary exposures to carbofuran, either from food or drinking water. JA-339-44.

The remaining domestic carbofuran uses have few, if any, effective alternatives, and the economic impact of banning carbofuran is therefore significant. Banning carbofuran is estimated to cost growers, applicators, vendors, and the downstream farm economies $86-254 million from the loss of carbofuran on corn, $56-190 million from its loss on potatoes, and $13-22 million from its loss on sunflowers. JA-201, 208-09, 214.[2]

### B. Proceedings Below

#### 1. *Proposed Revocation And Comments*

On July 31, 2008, EPA proposed to revoke carbofuran's tolerances under the FFDCA—an action that would effectively ban any domestic carbofuran use. *See generally* 73 Fed. Reg. 44,864 (July 31, 2008). EPA has admitted that there is *no* danger from carbofuran residues on food. *See, e.g.*, App.343a-45a; App.14a. As a result, EPA's proposed tolerance revocation rested on one narrow basis: potential exposures from drinking water drawn from ground or surface water sources. App.345a-47a.

In response to EPA's proposed tolerance revocation order, petitioners submitted extensive comments and supporting extensive evidence—including expert analyses—demonstrating that exposures from surface and drinking water were safe, and contesting EPA's estimates of exposure levels and the safe dosage of

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[2] Carbofuran also has tolerances approved by EPA for imported crops of sugarcane, coffee, bananas, and rice. EPA has admitted that residue levels on these crops are safe. App.14a.

carbofuran (which all parties agree is non-zero). *See generally* JA-601-775. At the same time, to address any potential concerns about possible water exposures, petitioners voluntarily cancelled most carbofuran uses, App.457a-59a, restricted the geographic areas where carbofuran could be used, App.465a-66a, 476a-77a, and reduced the maximum application rates for particular crops. App.477a-78a. Petitioners also provided data showing that carbofuran usage would not exceed 4.25% in *any* watershed, and that, based on EPA's own modeling, such usage levels were safe. App.448a-49a.

2. ***Final Revocation Order***

EPA published a final revocation order on May 15, 2009, with an effective date of December 31, 2009. 74 Fed. Reg. 23,046, 23,088 (May 15, 2009). Ignoring petitioners' data showing that carbofuran usage did not exceed 4.25% in any watershed, EPA assumed that *100%* of crops that could be treated with carbofuran would be so treated, simply because it "remains legally permissible for 100% of [a given watershed] to be treated with carbofuran." App.350a. Based on that unrealistic assumption, EPA concluded that carbofuran usage did not meet the FFDCA safety standard. App.235a-36a, 4a-8a. In response to petitioners' comments, EPA also adjusted its groundwater modeling using a new, so-called "Wisconsin scenario" that changed the agency's analysis for determining when usage levels were safe. App.362a-65a.

3. ***Objections And Request For A Hearing***

Petitioners filed extensive objections and supporting exhibits challenging EPA's revocation order—and requested a hearing on their objections. *See* App.440a-503a. Petitioners challenged many of the core factual assumptions underlying EPA's revocation

order, proffered extensive evidence and testimony from experts in support of each challenge, and requested a hearing on several outcome-determinative factual issues centered around whether exposures to carbofuran are safe. JA-1145-89. In response to EPA's new "Wisconsin scenario" and assumption of 100% usage, petitioners also submitted a proposal (presented as label amendments under FIFRA) to impose a legally-binding limit on carbofuran usage to no more than 2% of acreage in a watershed, and mandatory setbacks from drinking water wells. *See, e.g.*, App.470a-76a. While petitioners' objections were pending, EPA admitted that there was no imminent danger from current carbofuran use—stating, for example, that "'there is little exposure today,'" and acknowledging that under EPA's own assumptions carbofuran "would rarely pose a risk." Juliet Eilperin, *In Surprise Move, EPA Bans Carbofuran Residue on Food*, Washington Post, July 25, 2008.

5. ***EPA Denial Of Objections And Hearing Request***

Four-and-a-half months after petitioners filed their objections, EPA denied petitioners' objections and hearing requests. *See* App.16a-342a. Although EPA acknowledged that EPA's regulations (40 C.F.R. § 178.32(b)) established a "summary judgment-type" standard for determining when a hearing is required modeled on the hearing requirements at issue in *Weinberger*, App.82a-83a, EPA denied a hearing on bases wholly incompatible with *Weinberger* and any "summary judgment-type" procedure—freely drawing inferences in its own favor, weighing the evidence itself, dismissing opposing experts' opinions without

challenging their qualifications, and rejecting evidence simply because *it* was not convinced to change course.[3]

EPA also categorically disregarded important aspects of petitioners' objections and submission. Although both the FFDCA (21 U.S.C. § 346a(g)(2)(A)) and the agency's own rules (40 C.F.R. § 178.20(a)) explicitly allow parties to raise objections *after* a final revocation order is issued, EPA declared that contentions raised in comments on EPA's *proposed* revocation were conclusively addressed in the final revocation order and thus refused to consider certain objections on the ground that they purportedly were "recycled." App.23a. At the same time, EPA deemed "too late" any data, issue, argument, or factual detail not specifically raised in petitioners' comments on the proposed revocation, even though EPA had a full opportunity to address these points in its extensive denial of objections and hearing request. *See* App.311a.

Tellingly, EPA even refused to consider objections to new positions adopted by EPA in its final revocation order that petitioners could not challenged earlier. For example, even though EPA first unveiled its new "Wisconsin scenario" in its final revocation order, EPA

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[3] EPA's order is replete with such analysis. *See, e.g.*, App.127a (weighing the "totality of the evidence" to deny petitioners' hearing request); *id.* (concluding "sum of [petitioners'] evidence ... falls far short"), App.152a (arguing "Petitioners' evidence does not demonstrate that reliance on juvenile brain data ... will guarantee that the levels chosen ... will be predictive [of effects]"), App.182a (rejecting "Petitioners' suggested approach" because, in its judgment, it was "scientifically invalid"), App.207a (contending "evidentiary proffer does not support their contention"); App.209a (arguing evidence "provided is insufficient to allow EPA to confirm the Petitioners' contention"); App.218a (concluding "evidentiary proffer in support of this objection is inadequate").

refused to consider petitioners' proposed use of setbacks from drinking wells to address this new modeling scenario on the ground that the objection was "too late" because it was not raised in petitioners' comments. But petitioners' comments could not have addressed a modeling scenario introduced for the first time in EPA's revocation order. *See* App.60-63a.

6. ***District Of Columbia Circuit Decision***

Petitioners sought review of EPA's revocation order and challenged, *inter alia*, EPA's denial of a hearing. The District of Columbia Circuit affirmed EPA's hearing denial order in broad terms. App.1a-15a. The court recognized that "the FFDCA and the EPA's regulations establish a 'summary-judgment type' standard for determining whether to hold a hearing: The EPA must hold a hearing if it determines an objection raises a material issue of fact." App.6a. However, the court declined seriously to entertain whether the agency actually applied a "'summary-judgment type' standard," and adopted a "necessarily deferential" standard for reviewing the agency's denial of a hearing request. App.6a-7a. The court also upheld EPA's refusal to consider objections based on EPA's newfound, Catch-22 timing rules. App.8a-13a.

The District of Columbia Circuit's standard of review looked only to "'whether [the agency] has given adequate consideration to all relevant evidence,'" and thus effectively gave the agency *carte blanche* to decide "'factual matters'" within the agency's area of expertise. App.7a (alteration in original) (citations omitted). Applying that standard, the court affirmed EPA's 100% usage assumption for surface water, even though petitioners' expert data showed that actual usage did not exceed 4.25% in any relevant area. And

the court held that an admitted "dispute between experts" was "*fatal*" to petitioners' request for a hearing. App.13a (emphasis added). In the court's view, neither a dispute among accredited experts nor "'differences in the weight or credence given to particular scientific studies'" were sufficient to create a material dispute of fact. *Id.* (citation omitted).[4]

7. ***EPA's Subsequent Hearing Denial***

EPA wasted little time in pressing the District of Columbia Circuit's decision in this case into service of its four-decade-long refusal to hold hearings, using it to support EPA's denial of a hearing request by the Natural Resources Defense Council (NRDC) on its petition seeking the revocation of tolerances for the pesticide carbaryl. 75 Fed. Reg. 55,997 (Sept. 15, 2010). EPA's order cites the District of Columbia Circuit's decision in this case in both narrowing the objections that the agency considered and in arrogating to the agency the authority to weigh the evidence itself, make credibility determinations, and simply disregard contrary expert evidence. *Id.* at 56,007, 56,010-12.

## REASONS FOR GRANTING THE WRIT

The District of Columbia Circuit's decision in this case upholding EPA's refusal to grant an evidentiary hearing under the FFDCA before banning a product used safely for decades warrants this Court's review for three principal reasons. First, the court's conception of when a hearing is required under the

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[4] In light of EPA's own admission that the import tolerances for carbofuran were "safe," the panel set aside EPA's revocation of those tolerances as "requir[ing] no display of learning." App.14a. That ruling is not challenged here.

FFDCA conflicts not only with the agency's own rules establishing that a "'summary-judgment type' standard" (App.6a) governs, but with this Court's decision in *Weinberger v. Hynson, Wescott & Dunning, Inc.*, 412 U.S. 609 (1973), and with the decisions of other circuits. Second, the court's endorsement of EPA's novel rule allowing the agency categorically to reject objections as either "too early" or "too late" compounds the damage done by the court's ruling on when a hearing is due, directly contravenes the FFDCA and EPA's own rules, and conflicts with the decisions of this Court and other circuits on when an agency may invoke waiver. And third, the court's decision eviscerates a critical statutory right designed to protect the public in a wide array of matters of great economic and public policy significance.

## I. THE DISTRICT OF COLUMBIA CIRCUIT'S DECISION ON THE STANDARD FOR WHEN A HEARING IS REQUIRED UNDER THE FFDCA MERITS THIS COURT'S REVIEW

Nearly four decades ago, in *Weinberger*, this Court approved the use of administrative summary-judgment procedures under the FFDCA. But in doing so, the Court articulated important limits on that power to ensure that those procedures remained faithful to the bedrock principles of summary judgment and that agencies—which invariably regard evidentiary hearings before neutral factfinders as an unwelcome intrusion on their decision-making—did not abuse those procedures and thereby render parties' right to a hearing a nullity. *See* 412 U.S. at 620-23. The decision below vitiates those important safeguards, conflicts

with *Weinberger* and decisions of other courts, and effectively eviscerates this important hearing right.

### A. The Decision Below Is Fundamentally Incompatible With Any "'Summary-Judgment Type' Standard" And Nullifies The FFDCA's Hearing Right

1. As the court of appeals observed, "[t]he parties agree that the FFDCA and the EPA's regulations establish a 'summary-judgment type' standard for determining whether to hold a hearing: The EPA must hold a hearing if it determines an objection raises a material issue of fact." App.6a; *see* App.82a (recognizing that EPA's regulations adopt "summary judgment-type procedures" under which a hearing is available for "disputed material factual issues"). The court of appeals' decision, however, is fundamentally incompatible with any "'summary-judgment type' standard." Indeed, the court's decision eliminates what the court itself recognized is the hallmark of any summary judgment-type procedure: the entitlement to a hearing to resolve disputed issues of material fact. The decision below likewise contravenes a central purpose of FFDCA § 408(g): to require that disputes over material issues be tested by the adversarial process, rather than allowing EPA to cherry pick opinions supporting its preferred outcome.

2. As the agency has frankly observed, EPA views hearings under the FFDCA as "time-consuming" and "unnecessary," EPA D.C. Cir. Br. 5, 56 (filed Feb. 3, 2010)—in short, an unwelcome addition to, and intrusion into, the agency's own decision-making. As a result, although EPA's regulations indisputably adopt summary judgment-type procedures requiring a hearing to resolve disputed issues of material fact,

EPA has utterly disregarded those procedures and, tellingly, has *never* found a single issue of material fact on which it believed a hearing was required in the four decades it has administered the FFDCA.[5]

EPA's denial of a hearing on the record in this case flouts several essential features of any meaningful "summary judgment-type standard." *First*, a bona fide dispute among experts over material facts is a paradigmatic situation where a hearing is required. *See, e.g.*, *Phillips v. Cohen*, 400 F.3d 388, 399 (6th Cir. 2005); *Trunk v. City of San Diego*, Nos. 08-56415, 08-56436, 2011 U.S. App. LEXIS 53, at *35 n.12 (9th Cir. Jan. 4, 2011). Here, the court of appeals recognized that both sides had presented expert testimony on outcome determinative, and thus material issues, such as the concentration of carbofuran in groundwater. App.11a-13a. Yet, the District of Columbia Circuit—turning this bedrock summary judgment principle on its head—held that a "'dispute between experts'" was "fatal" to obtaining a hearing. App.13a.

*Second*, another classic feature of any "summary judgment-type" procedure is that "all justifiable inferences are to be drawn" against the party opposing a trial/hearing (here, EPA). *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). But the court of appeals permitted EPA to deny a hearing by drawing the patently absurd inference that crop treatment

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[5] *See, e.g.*, 75 Fed. Reg. 55,997 (denying hearing); 73 Fed. Reg. at 42,710 (same) ("EPA has not held any pesticide tolerance hearings under the FFDCA."); 53 Fed. Reg. 41,126, 41,127 (Oct. 19, 1988) (same); 72 Fed. Reg. 39,318, 39,323-24 (July 18, 2007) (denying hearing request); 59 Fed. Reg. 33,684 (June 30, 1994) (same).

levels would be *100%* in a watershed, even though petitioners' experts showed that actual usage did not exceed 4.25% in any relevant area—a factual issue that is outcome-determinative as to the safety of exposures from surface water. App.7a, 10a-11a, 449a-54a. Indeed, even EPA admitted that its assumption of 100% usage was "unlikely ... [to occur] in most watersheds." App.235a-36a; *accord* App.349a. To say the least.

*Third*, it is well-settled that, in determining whether to hold a hearing, a "judge's function is not himself to weigh the evidence." *Anderson*, 477 U.S. at 249. But in denying a hearing, EPA repeatedly did just that, acting as both a litigant *and* judge and denying a hearing on the ground that *it* was not persuaded to alter its own decision. *See, e.g.*, App.127a-28a, 152a, 182a, 207a, 209a-10a, 291a. The District of Columbia Circuit acquiesced—holding that "'[m]ere differences in the weight'" of the evidence could not justify a hearing. App.7a (citation omitted). Yet differences in the weight of evidence that can justify different outcomes are often precisely why our system requires hearings and trials. *Anderson*, 477 U.S. at 255 ("[T]he weighing of the evidence ... [is a] jury function[], not [one] of a judge ...."). And if Congress had wanted to give EPA free rein to make such determinations it would not have required hearings before *neutral* arbiters to resolve disputed issues of material fact.

3. Instead of enforcing the "'summary judgment-type' standard" that the court of appeals itself recognized was established by EPA's own rules, the court held that its review of EPA's hearing denial was "necessarily deferential" and then broadly deferred to EPA's decision that a hearing was not required. App.6a-7a. There are several fundamental problems

with that approach. First, as explained in the next section, the District of Columbia Circuit's highly deferential standard of review directly conflicts with this Court's decision in *Weinberger*. Second, no measure of deference—not even arbitrary-and-capricious review—may excuse the denial of a hearing under a legally erroneous standard. *See, e.g.*, *Mountain Side Mobile Estates P'ship v. Secretary of HUD*, 56 F.3d 1243, 1250 (10th Cir. 1995); *cf.* 5 U.S.C. § 706(2). And third, an agency decision must be set aside if it does not meet statutory or regulatory requirements. *See Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 413-14 (1971). Here, EPA's denial of a hearing was based on a standard that flouts the "'summary judgment-type' procedures" undeniably required by the agency's own rules. App.82a-83a.

4. The upshot is that the court of appeals' decision essentially eviscerates the hearing right under the FFDCA and the agency's own rules. As the Fourth Circuit observed in refusing to permit an agency to engage in the same sort of tactics to deny a hearing under the very procedures on which EPA's summary judgment-type standard was modeled, if the "predicate for securing [the] right to a hearing" is that the proponent's evidence must be sufficient to convince the agency to change its decision—not just sufficient to create a material issue of disputed fact—then "a hearing would be useless and the Congressional promise of a hearing would be purely illusory." *Hynson, Westcott & Dunning, Inc. v. Richardson*, 461 F.2d 215, 220 (4th Cir. 1972) ("*Hynson*"). EPA's hearing denial on the record here likewise renders the FFDCA's hearing requirement "purely illusory."

Commentators have long recognized that agencies have institutional incentives (like retaining control over their own decision-making process) to manipulate administrative summary-judgment procedures as a "hearing-avoidance technique." Charles C. Ames & Steven C. McCracken, *Framing Regulatory Standards to Avoid Formal Adjudication: The FDA As a Case Study*, 64 Cal. L. Rev. 14, 30 (1976) (heading); *see id.* (noting that FDA has succeeded in eliminating hearings over "all but the most unusual factual contentions"). EPA—which dismissively refers to hearings as "time-consuming" and "unnecessary," EPA D.C. Cir. Br. 5, 56, and in nearly 40 years has never held a hearing under the provision at issue—has taken this "hearing-avoidance technique" to the extreme.

The nullification of an Act of Congress ordinarily is a compelling reason for granting certiorari. *See, e.g.*, *United States v. Powell*, 423 U.S. 87, 88 (1975). It is a particularly strong reason here. The right to a hearing before a neutral and detached factfinder to resolve disputed issues of material fact is a vital and time-honored safeguard. As this case well illustrates, EPA—like other agencies—is not programmed to second-guess its own conclusions and institutional biases. *Cf. Ramaprakash v. FAA*, 346 F.3d 1121, 1122 (D.C. Cir. 2003) ("Learned Hand once remarked that agencies tend to 'fall into grooves, and when they get into grooves, then God save you to get them out.'") (Roberts, J.) (alteration and citation omitted). It is therefore critical that courts ensure that EPA at least abide by its own "summary-judgment type standard" in determining when a hearing before a neutral finder of fact is required to resolve material factual issues.

### B. The Decision Below Conflicts With This Court's Decision In *Weinberger* As Well As Decisions Of Other Circuits

1. The District of Columbia Circuit's decision flies in the face of this Court's seminal decision on administrative summary-judgment procedures in *Weinberger*. In *Weinberger*, this Court affirmed the Fourth Circuit's decision *reversing* FDA's denial of a hearing under the FFDCA in considering whether to withdraw approval of a new drug application. 412 U.S. at 616-23. As EPA explained in the challenged order, the "summary judgment-type procedures" governing the hearing requirement at issue in this case are "based heavily" on the procedures that this Court embraced in *Weinberger*. App.82a. The Court's decision in *Weinberger* therefore supplies a clear baseline for determining when a hearing is required under the "'summary-judgment type' standard" that indisputably (App.6a) governs the hearing requirement this case.

The decision below conflicts with *Weinberger* in three fundamental respects. *First*, in *Weinberger*, this Court recognized that administrative summary judgment is appropriate only "where it is apparent at the threshold that the applicant has not tendered *any* evidence which *on its face* meets the statutory standards as particularized by the regulations." 412 U.S. at 620 (emphasis added). This standard parallels the standard for granting summary judgment, under which a trial can be denied only if the record reveals "there can be but one reasonable conclusion as to the verdict." *Anderson*, 477 U.S. at 250. In this case, by contrast, the District of Columbia Circuit properly characterized the essence of the disagreement between petitioners and EPA as a "dispute between experts"

about dispositive facts. App.13a. But, as discussed, the court paradoxically reasoned that such a dispute was "fatal" to petitioners' hearing request. *Id.*

*Second*, in *Weinberger*, this Court made clear that a reviewing court should engage in a meaningful—and thus not unduly deferential—inquiry into whether a hearing was required. The Court admonished that, "[i]n reviewing an order of the Commissioner denying a hearing, a court of appeals must determine whether the Commissioner's findings accurately reflect the study in question and if they do, whether the deficiencies he finds conclusively render the study inadequate or uncontrolled in light of the pertinent regulations." 412 U.S. at 622. This standard of review ensures that an agency may properly deny a request for a hearing only "when it appears *conclusively* from the applicant's '*pleadings*' that the application cannot succeed," *id.* at 621 (emphases added), and thus squares with a customary summary judgment-type standard.

In contrast, the District of Columbia Circuit applied a "necessarily deferential" standard of review "'limited to an evaluation of whether [the agency] has given adequate consideration to all relevant evidence in the record.'" App.7a (citation omitted). And the answer even to this hands-off inquiry was all but preordained because the court refused to evaluate the agency's characterization of petitioners' expert evidence, stating instead that it "'will not substitute [its] judgment on highly technical and factual matters for that of the agency.'" *Id.* (citation omitted). But as *Weinberger* underscores, whatever deference an agency typically is owed on "highly technical" or scientific matters, agencies do not enjoy *carte blanche* in deciding whether there are material issues of disputed facts

over technical or scientific issues.

*Third*, in *Weinberger*, the Court admonished that the general rule that administrative summary judgment is warranted "when it appears conclusively from the applicant's 'pleadings' that the application cannot [satisfy the regulatory requirements for a hearing]," 412 U.S. at 621, "applies, of course, *only to those regulations that are precise*," such as a rule requiring a study to include "[a] summary of the methods of analysis," *id.* at n.17 (emphasis added). In contrast, the Court explained, more subjective, "qualitative standards"—like those directing applicants to produce "adequate" or "suitable" data—"do not lend themselves to clear-cut definition," and thus do not lend themselves to summary disposition. *Id.*

In this case, EPA has failed to provide any clear, objective standards that might support a conclusion that petitioners' proffer was "conclusively" inadequate on its face. Instead, EPA rejected petitioners' scientific evidence because it concluded there was not a "*reasonable possibility*" that petitioners' evidence was "[]*sufficient* to justify the factual determination urged." 40 C.F.R. § 178.32(b)(2) (emphasis added); *see, e.g.*, App.78a, 267-68a, 334a. But these are just the sort of inherently "qualitative"—and thus more subjective—standards that the *Weinberger* Court held were less amendable to administrative summary judgment. *See Weinberger*, 412 U.S. at 621 n.17.[6]

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[6] FDA—the agency upon whose regulations EPA's regulations are "heavily" based, App.82a—has "announced that, with regard to an imprecise regulation, a study would not conclusively be deemed inadequate unless it totally failed *'even to attempt to comply.'*" *Puerto Rico Aqueduct & Sewer Auth. v. EPA*, 35 F.3d 600, 606 (1st Cir. 1994), *cert. denied*, 513 U.S. 1148 (1995)

2.a. The District of Columbia Circuit's decision in this case also conflicts with the decisions of other circuits, including the Fourth Circuit's own decision in *Weinberger*—which retains precedential force because it was affirmed in relevant part by this Court. *See id.* at 634 (affirming *Hynson* with modification to unrelated aspect of opinion). Whereas the District of Columbia Circuit held below that "'differences in the weight or credence given to particular scientific studies'" are insufficient to obtain a hearing under the FFDCA, App.13a (citation omitted), the Fourth Circuit held in *Hynson* that a hearing was required under an analogous provision of the FFDCA precisely *because* FDA and the petitioners in that case disputed the weight to be given to several "clinical studies" and "investigations." 461 F.2d at 221. Indeed, the Fourth Circuit viewed FDA's denial of a hearing in such circumstances to be so egregious as to violate due process as well as the FFDCA. *Id.* at 220-21.[7]

Likewise, the Fourth Circuit ultimately determined that a hearing was required because the material issue of whether the drug at issue was effective was subject to conflicting expert testimony. The court observed that the agency's objections to the proponent's experts

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(emphasis added). Even EPA has not accused petitioners of failing to meet that standard.

[7] As Justice Powell observed in *Weinberger*, "[t]here is also a genuine issue of procedural due process where, as in this case, the Commissioner construes his regulations to deny a hearing" where the party seeking a hearing has submitted significant evidence and expert opinions. 412 U.S. at 638 (concurring in part and concurring in the result in part). EPA's order here denying a hearing despite the ample evidence and expert data submitted by petitioners suffers from the same due process defect.

might be well-grounded, but they did not justify the denial of a hearing—"they merely create[d] a genuine question of fact to be resolved at a hearing upon proper evidence" and an examination of the experts. 461 F.2d at 221-22. In stark contrast, the District of Columbia Circuit in this case concluded that "differences in the weight or credence given to particular scientific studies" provide no basis for requiring an agency to conduct a hearing and that, quite the contrary, "a dispute between experts" over a critical issue is "fatal" to a proponents' hearing request. App.13a.

b. The District of Columbia Circuit's decision in this case also is at odds with the Ninth Circuit's decision in *Pactra Industries, Inc. v. Consumer Products Safety Commission*, 555 F.2d 677 (1977) (Kennedy, J.). In *Pactra*, the Ninth Circuit considered a separate provision of the FFDCA that incorporated the same basic "'summary-judgment type' standard" that applies to the FFDCA provision in this case, App.6a, and held that the agency must hold a hearing if it determines an objection raises a material issue of fact, *see Pactra*, 555 F.2d at 684. Under this standard, the Ninth Circuit held, a hearing may not be denied "merely because *the agency* has concluded that the scientific evidence is adequate to support its order"; instead, objections that "are neither frivolous nor inconsequential" and that concern key safety matters "raise material issues that should not be dispelled at the outset without a hearing." *Id.* (emphasis added). In this case, by contrast, the District of Columbia Circuit refused to recognize that well-supported objections raised material issues of fact and deferred entirely to the agency's own view that disputed evidence was sufficient to support its order.

c. The District of Columbia Circuit's decision likewise conflicts with the decisions of other circuits recognizing that "inherent in the very concept of administrative summary judgment" is that a "genuine and material dispute" over facts is sufficient "to qualify for an evidentiary hearing." *Puerto Rico Aqueduct & Sewer Auth. v. EPA*, 35 F.3d 600, 605 (1st Cir. 1994), *cert. denied*, 513 U.S. 1148 (1995) ("*PRASA*"). Indeed, as the First Circuit has observed, "[a]ny other assumption borders on the chimerical." *Id.*; *see also, e.g., Crestview Parke Care Ctr. v. Thompson*, 373 F.3d 743, 755 (6th Cir. 2004) ("In evaluating whether [administrative] summary judgment is proper, we do not weigh the evidence, but rather view the evidence in the light most favorable to [the hearing applicant] to divine the existence of a genuine dispute of material fact"); *J.D. ex rel. J.D. v. Pawlet Sch. Dist.*, 224 F.3d 60, 69 (2d Cir. 2000) (administrative summary-judgment procedure proper under IDEA "where the parties have had a meaningful opportunity to present evidence and the non-moving party is unable to identify any genuine issue of material fact"); *Travers v. Shalala*, 20 F.3d 993, 998 (9th Cir. 1994) (agreeing that an administrative hearing is unnecessary where there are "no disputed issues of material fact"); *E.R. Squibb & Sons, Inc. v. Weinberger*, 483 F.2d 1382, 1386 (3d Cir. 1973) (concluding that, "[b]efore this Court may affirm an action taken by summary judgment [under the FDA regulations], it must be certain that no genuine issues as to any material facts are in dispute"). As discussed, the District of Columbia Circuit's decision in this case sharply departs from that understanding.[8]

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[8] The text of the statutory hearing requirements at issue in this

3. As this Court has observed, a "principal purpose" of this Court's "certiorari jurisdiction ... is to resolve conflicts among the United States courts of appeals." *Braxton v. United States*, 500 U.S. 344, 347 (1991); *see* Sup. Ct. R. 10(a). Certiorari is also appropriate to resolve conflicts with the decisions of this Court. *See* Sup. Ct. R. 10(c). The conflicts created by the decision below and this Court's decision in *Weinberger* as well as the decisions of other circuits discussed above warrant certiorari here.

## II. THE DISTRICT OF COLUMBIA CIRCUIT'S ENDORSEMENT OF EPA'S EXTRAORDINARY "CATCH-22" WAIVER RULE MERITS THIS COURT'S REVIEW

The District of Columbia Circuit compounded the damage done by its ruling on the standard for obtaining a hearing under the FFDCA by endorsing EPA's extraordinary timing rule governing what objections need be considered at all by the agency. Under this Orwellian scheme, arguments first presented *before* EPA's proposed revocation order may be deemed "recycled" (and therefore "irrelevant") when it comes to seeking a hearing on a final revocation order, while arguments first presented *after* the final revocation order in seeking a hearing may be deemed "untimely" and "waived." App.310a-13a, 23a-24a. EPA's new waiver rule thus creates a whip saw for parties seeking

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case, *Weinberger*, and the circuit cases discussed above varies in some respects. But critically, the administering agencies all (correctly) recognize that these provisions require a hearing when there are material issues of disputed fact and have promulgated nearly identical administrative summary-judgment procedures to that effect. *See* App.6a; *Weinberger*, 412 U.S. at 616, 621-22; *Pactra*, 555 F.2d at 684; *E.R. Squibb & Sons*, 483 F.2d at 1384.

a hearing and allows the agency arbitrarily to disregard timely submitted evidence and expert data establishing material issues of disputed fact as either "too early" or "too late." The District of Columbia Circuit's decision embracing that absurd rule conflicts with the decisions of this Court and other circuits, and thus underscores the need for review in this case.[9]

### A. EPA's "Catch-22" Waiver Standard Violates The FFDCA And The Agency's Own Regulations

EPA's remarkable "Catch-22" waiver rule violates the text of both the FFDCA and EPA's own regulations. The FFDCA expressly provides that a party "may file objections" "*after* a regulation or order [of revocation] is issued" and never requires also raising them in comments. 21 U.S.C. § 346a(g)(2)(A) (emphasis added). By expressly allowing comments to be raised "after" EPA's final order of revocation, the FFDCA precludes agency forfeiture of arguments on the basis that they were not raised before then. *See, e.g., Jama v. Immigration & Customs Enforcement*, 543 U.S. 335, 341 (2005) ("We do not lightly assume that Congress has omitted from its adopted text requirements that it nonetheless intends to apply ....").

Likewise, EPA's own regulations permit objections to be raised "[o]n or before the 60th day *after the date of publication.*" 40 C.F.R. § 178.20(a) (emphasis added). And the agency expressly provides that "EPA

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[9] This defect provides an additional basis for granting certiorari. Even if EPA properly excluded objections under its newfound and *ultra vires* waiver rule, a hearing was still required based on the objections and evidence that EPA *did* consider, which in itself is sufficient to establish a material issue of disputed fact.

does not interpret the statute and regulations to preclude the submission of *any new* information as part of the objections phase." App.111a (emphasis added). Notwithstanding these rules, the agency repeatedly and specifically refused to consider evidence or objections responding to EPA's final revocation order. *See, e.g.*, App.210a, 233a, 262a, 267a.

Remarkably, EPA even precluded petitioners from raising objections or evidence to support a hearing request that responded to a *change* in EPA's reasoning between the proposed and final orders. For example, EPA's proposed tolerance revocation *assumed* that *100%* of crops would be treated with carbofuran. App.434a. Petitioners countered with data showing that actual usage had not exceeded *4.25%* in the past decade. App.434a-39a, 449a. In the final revocation order, EPA—for the first time—justified its 100% usage assumption on the basis that, even if exceedingly unlikely and never documented, it is "legally permissible" and thus must be considered in its risk assessment. App.235a-36a. Petitioners' objections to the proposed revocation addressed this new rationale by proposing to adopt a "cap on usage" that would make it *legally impermissible* to treat more than 2% of a watershed. App.448a, 451a-52a. The usage cap was outcome-determinative, as it would have assured that surface water exposures were within safe levels. App.448a. Yet, even though this objection was submitted in response to a new rationale in EPA's final revocation order, the District of Columbia Circuit held that EPA was free to disregard it. App.11a.

Similarly, for groundwater exposures—another outcome-determinative issue of fact disputed by petitioners—EPA advanced a new rationale for the

first time in its final revocation order: *i.e.*, that new modeling of leaching to groundwater in Wisconsin conducted in response to petitioners' comments showed that carbofuran still posed a groundwater risk. App.61a-63a. In response, petitioners' objections proposed "setbacks," which would assure a safe level of groundwater exposures notwithstanding EPA's new Wisconsin scenario. App.444a-45a, 485a-90a. Yet, the District of Columbia Circuit again upheld EPA's claim that the proposal was untimely, App.112a-18a, without even addressing the fact that the setback proposal was submitted to address grounds raised by EPA for the first time in its final order, App.362a-63a, 441a-42a.

EPA's new waiver rule—which grants the agency virtually unfettered discretion to pick and choose what objections it wishes to consider, or simply disregard, in considering hearing requests—exudes arbitrary agency action. *Cf. Ramaprakash,* 346 F.3d at 1130 ("'[T]he core concern underlying the prohibition of arbitrary or capricious agency action' is that agency 'ad hocery' is impermissible") (Roberts, J.). And the dangers of that rule are neither theoretical nor isolated. Indeed, EPA invoked this extraordinary rule less than two months after the District of Columbia Circuit's decision in this case to deny NRDC's request for a hearing under the FFDCA. *See* 75 Fed. Reg. 55,997, 56,010-11 (Sept. 15, 2010). And armed with this new rule, EPA can dismantle any hearing request.

### B. In This Respect Too, The Decision Below Conflicts With The Decisions Of This Court And Other Circuits

The District of Columbia Circuit's decision upholding that novel waiver rule is at odds with the core principles underlying the decisions of this Court

and other circuits on administrative exhaustion.

As this Court held in *Sims v. Apfel*, 530 U.S. 103, 107 (2000), "requirements of administrative issue exhaustion are largely creatures of statute." But as explained, the statute at issue—the FFDCA—imposes no exhaustion requirement. Nor do any of the agency's own regulations. To the contrary, EPA's regulations explicitly provide that parties may raise arguments "after" the comment stage. *Supra* at 27; *see Sims*, 530 U.S. at 113 (O'Connor, J., concurring in part and concurring in the judgment) ("Requiring issue exhaustion is particularly inappropriate here, where the regulations and procedures of the [agency] affirmatively suggest that specific issues need not be raised before the Appeals Council."). Neither EPA nor the District of Columbia Circuit was free retroactively to impose new issue exhaustion requirements in this case where governing "regulations do not require [such] issue exhaustion." *Sims*, 530 U.S. at 108.[10]

The decision below also conflicts with the decisions of other circuits. The Ninth Circuit, for example, has held that it is sufficient to defeat a claim of waiver that an agency merely "understood plaintiffs to raise the issue of whether [it] complied with [the relevant statute]." *Native Ecosystems Council v. Dombeck*, 304 F.3d 886, 899 (9th Cir. 2002); *see also id.* (A party need only "afford [the agency] the opportunity to rectify the

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[10] While this Court has, on occasion, permitted "issue-exhaustion requirement[s]," they have largely followed from "analogy to the rule that appellate courts will not consider arguments not raised before trial courts." *Sims*, 530 U.S. at 108-09; *see also Dep't of Transp. v. Public Citizen*, 541 U.S. 752, 764 (2004). Here, there can be no doubt that petitioners had raised all relevant arguments before EPA, and that EPA was alerted to them.

violations ... alleged."); *Forest Guardians v. United States Forest Serv.*, 495 F.3d 1162, 1170-73 (10th Cir. 2007) (citing *Dombeck* with approval). And even if that minimal requirement is not met, the Ninth Circuit has held that it will consider arguments *never* raised before an agency as long as the agency had "independent knowledge of the issues that concerned [petitioners]." *'Ilio'Ulaokalani Coal. v. Rumsfeld*, 464 F.3d 1083, 1092-93 (9th Cir. 2006). The Third Circuit similarly requires only that an agency "was on notice of, and had an opportunity to consider and decide, the same claims now raised in federal court." *Kleissler v. United States Forest Serv.*, 183 F.3d 196, 202 (3d Cir. 1999).

EPA has never denied that it had both notice and an opportunity to consider petitioners' objections, including their label amendments. EPA simply refused to do so. In at least the Third and Ninth Circuits, EPA's arbitrary waiver rule would not be enforced. But in stark contrast, the District of Columbia Circuit blessed EPA's rule requiring that petitioners raise all arguments twice, at both stages of proceedings—although petitioners will still run headlong into EPA's other waiver whip-saw, by purportedly "recycling" the argument/data at the second stage. That conflict of authority also warrants this Court's review.

## III. THE QUESTION PRESENTED HAS FAR-REACHING SIGNIFICANCE AND IS UNDENIABLY IMPORTANT

This case concerns a matter of exceptional national importance. For more than four decades, EPA has thwarted Congress's express hearing requirement under the FFDCA—implausibly failing to identify a single disputed material fact that it believed justified a hearing. It is safe to say that EPA has never seen a

hearing request it likes—and never will. EPA's obstinac in refusing to give effect to the FFDCA's hearing requirement and its own summary-judgment procedures is if anything even more institutionalized and evident than was FDA's before this Court granted certiorari in *Weinberger*, and thus is even more worthy of review and repudiation by this Court.

Nor is the damage limited to EPA and pesticides. The FFDCA hearing requirement and administrative summary-judgment procedures at issue in this case are comparable to other hearing requirements administered by EPA, FDA, and CPSC concerning an array of important products and goods: from medical devices, prescription drugs, agriculture, food and food additives and cosmetics, to a myriad of consumer goods. Given that such products account for a substantial portion of the national economy, Congress understandably desired greater procedural protections for regulatory decisions concerning the availability of such products. Moreover, these protections are particularly important where, as here, an agency seeks to ban a product that regulated parties like petitioners have been selling or using safely for many years.

The District of Columbia Circuit's willingness to accept uncritically EPA's unrealistic assumptions underscores the need for review by this Court. EPA's assumption of 100% carbofuran usage, for example, is not supported by *any* record evidence and instead is squarely contradicted by petitioners' evidence that actual usage did not exceed 4.25% in *any* relevant area. *Supra* at 9. But by adopting such fantastic assumptions, EPA—with the blessing of the District of Columbia Circuit—may ban virtually any product it dislikes, threatening *all* of the protections of the

FFDCA. After all, under such unrealistic modeling, everything from caffeine to water is potential deadly. And if EPA's 100% carbofuran usage assumption in this case is sufficient to withstand a hearing request, then EPA also presumably could regulate automobile emissions under a model where all cars will be driven hundreds of miles a day, for example—which is also perfectly legal and yet just as unrealistic as the assumption on which the hearing was denied here.

The fact that this case was decided by the District of Columbia Circuit heightens the importance of the ruling under review. The District of Columbia Circuit—with its nearly ubiquitous jurisdiction over administrative agencies—unquestionably exerts enormous influence on the field of administrative law. *See* John G. Roberts, Jr., *What Makes the D.C. Circuit Different? A Historical View*, 92 Va. L. Rev. 375, 389 (2006) ("Whatever combination of letters you can put together [in an agency's name], it is likely that jurisdiction to review that agency's decision is vested in the D.C. Circuit."); Richard J. Pierce, Jr., *The Special Contributions of the D.C. Circuit to Administrative Law*, 90 Geo. L.J. 779, 779 (2002) ("[T]he D.C. Circuit has long dominated and played a major role in shaping" administrative law).

This Court itself has recognized the heightened impact that decisions of the District of Columbia Circuit have on agency action. As the Court has observed, because "the vast majority of challenges to administrative agency action are brought to the ... District of Columbia Circuit ... the decision of that court ... will serve as precedent for many more proceedings for judicial review of agency actions than would the decision of another Court of Appeals."

*Vermont Yankee Nuclear Power Corp. v. NRDC*, 435 U.S. 519, 535 n.14 (1978); *see also* John M. Golden, *The Federal Circuit and the D.C. Circuit: Comparative Trials of Two Semi-Specialized Courts*, 78 Geo. Wash. L. Rev. 553, 562 (2010) (noting that this Court has historically "prioritized review of the D.C. Circuit's administrative law"). That holds true for review of agency orders denying evidentiary hearings as well.

In *Weinberger*, the Solicitor General advised this Court that the question presented in that case—which concerned when an evidentiary hearing is required under an analogous provision of the FFDCA and administrative summary-judgment procedures governing FDA's licensing of new drugs—was of "great importance" to FDA, the "drug industry," and "American consumer." Pet. for Cert. 20, *Weinberger*, 412 U.S. 609 (1973) (No. 72-394). The same goes for the agency, industries, and Americans affected by the hearing requirement at issue in this case concerning the safety of pesticides, not to mention the agencies, industries, and Americans affected by the many analogous hearing provisions discussed above.

Of course, here, from the government's perspective, the shoe is on the other foot compared to *Weinberger* (where the government sought review of a decision holding that a hearing was *required* under the same type of administrative summary-judgment procedures at issue here). But the question presented is no less important when it comes to ensuring that the public's right to a hearing is respected. Indeed, the Court's intervention is if anything even more warranted here.

## CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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FEBRUARY 16, 2011

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Supreme Court, U.S.
FILED

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OFFICE OF THE CLERK

No.

# In the Supreme Court of the United States

NATIONAL CORN GROWERS ASSOCIATION, ET AL.,
*Petitioners,*

v.

U.S. ENVIRONMENTAL PROTECTION AGENCY, ET AL.,
*Respondents.*

ON PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

## APPENDIX TO PETITION FOR A WRIT OF CERTIORARI

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TABLE OF CONTENTS

Page

Opinion of the United States Court of Appeals for the District of Columbia Circuit, *National Corn Growers Ass'n v. EPA*, 613 F.3d 266 (D.C. Cir. 2010) ..... 1a

Carbofuran; Order Denying FMC's Objections and Requests for Hearing, 74 Fed. Reg. 59,608 (Nov. 18, 2009) (omitting "References" section) ..... 16a

Carbofuran; Final Tolerance Revocations, 74 Fed. Reg. 23,046 (May 15, 2009) (excerpts) ..... 343a

Carbofuran; Proposed Tolerance Revocations, 73 Fed. Reg. 44,864 (July 31, 2008) (excerpts) ..... 369a

Order Denying Motion for Stay, *National Corn Growers Ass'n v. EPA*, No. 09-1284 (D.C. Cir. Dec. 14, 2009) ..... 377a

Order Denying Rehearing, *National Corn Growers Ass'n v. EPA*, No. 09-1284 (D.C. Cir. Oct. 19, 2010) ..... 380a

Order Denying Rehearing En Banc, *National Corn Growers Ass'n v. EPA*, No. 09-1284 (D.C. Cir. Oct. 19, 2010) ..... 381a

21 U.S.C. § 346a (omitting footnotes) ..... 382a

TABLE OF CONTENTS—Continued

Page

40 C.F.R. § 178.20 ..... 429a

40 C.F.R. § 178.30 ..... 430a

40 C.F.R. § 178.32 ..... 432a

Comments in Opposition to Proposed Tolerance Revocations for Carbofuran, submitted by the National Potato Council, National Corn Growers Association, National Cotton Council, National Sunflower Association, and FMC Corporation (Sept. 29, 2008) (excerpts) ..... 434a

Objections to the Final Order Revoking Tolerances for Carbofuran, and Request for Public Evidentiary Hearing, with exhibits (June 30, 2009) (excerpts) ..... 440a

Exhibit 1 (excerpts) ..... 456a
Exhibit 2 (excerpts) ..... 464a
Exhibit 3 (excerpts) ..... 469a
Exhibit 13 excerpts) ..... 484a
Exhibit 15 (excerpts) ..... 491a
Exhibit 18 (excerpts) ..... 501a

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT.

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NATIONAL CORN GROWERS ASSOCIATION, et al., Petitioners

v.

ENVIRONMENTAL PROTECTION AGENCY and Lisa Perez Jackson, Administrator, Respondents.

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No. 09-1284.

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Argued March 22, 2010.
Decided July 23, 2010.

613 F.3d 266

Before: GINSBURG, TATEL and GRIFFITH, Circuit Judges.

Opinion for the Court filed by Circuit Judge GINSBURG.

GINSBURG, Circuit Judge:

The National Corn Growers Association, the National Sunflower Association, the National Potato Council, and FMC Corporation petition for review of the order of the Environmental Protection Agency denying their objections to the EPA's Final Regulation revoking all "tolerances" for the pesticide carbofuran. We grant the petition for review in part and accordingly vacate the EPA's final rule to the extent it revoked import tolerances for carbofuran. We deny the petition for review in all other respects.

## I. Background

The EPA regulates pesticides pursuant to two federal statutes: the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136 *et seq.*, and the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. § 356a. The FIFRA establishes a registration system under which the EPA controls the sale, distribution, and use of pesticides. No one may sell a pesticide unless it has been properly registered with the EPA, pursuant to the FIFRA, for a particular use, which requires showing that, so used, the pesticide will not cause "unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5)(C).

Pursuant to the FFDCA, the EPA determines the maximum amount of a pesticide residue, which the statute terms a "tolerance," that may remain on or in raw and processed food. The EPA may establish or leave in effect a tolerance only if it is "safe," that is, only if

> there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.

21 U.S.C. § 346a(b)(2)(A). Absent an exemption from the Administrator of the EPA pursuant to § 346a(c), a provision not here at issue, any food containing a pesticide residue that exceeds an established tolerance is deemed "unsafe" and "adulterated" and may not be moved in interstate commerce. *Id.* §§ 331, 342(a)(2)(B).

The agency is required to modify or revoke an existing tolerance it later determines is not safe, *id.* § 346a(b)(2)(A)(i), which it does by way of a multi-step process. First, in what we refer to as the "comment

stage," it publishes a notice of the proposed revocation, provides a period for public comment and, having taken the comments into consideration, issues a "Final Regulation." *Id.* § 346a(e). Second, in what we refer to as the "objection stage," any person may file an "objection" to and request a public evidentiary hearing on the Final Regulation, after which the EPA issues an order stating the action taken upon each such objection and request and "setting forth any revision to the regulation ... the Administrator has found to be warranted." *Id.* § 346a(g)(2). The FFDCA requires that an objection "specify[ ] with particularity the provisions of the regulation ... deemed objectionable and stat[e] reasonable grounds therefor." *Id.* § 346a(g)(2)(A). The Act requires the EPA to hold a hearing only "if and to the extent the Administrator determines that such a public hearing is necessary to receive factual evidence relevant to material issues of fact raised by the objections." *Id.* § 346a(g)(2)(B). Under the EPA's implementing regulations:

> A request for an evidentiary hearing will be granted if the Administrator determines the material submitted shows the following:
>
> (1) There is a genuine and substantial issue of fact for resolution at a hearing. An evidentiary hearing will not be granted on issues of policy or law.
>
> (2) There is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor.... An evidentiary hearing will not be granted ... if the Administrator concludes that the data and information submitted, even if accurate, would be insufficient to justify the factual determination urged.

> (3) Resolution of the factual issue(s) in the manner sought ... would be adequate to justify the action requested. An evidentiary hearing will not be granted on factual issues that are not determinative with respect to the action requested.

40 C.F.R. § 178.32(b).

In 2006 the EPA concluded, in a dietary risk assessment, that human exposure to carbofuran, a pesticide used to control insect infestations in a number of crops, is "above the Agency's level of concern."* The EPA sought to limit exposure to carbofuran by revoking all tolerances under the FFDCA, which action would effectively ban the use of carbofuran on both domestic and imported food for human consumption. Referencing its earlier risk assessment, the EPA stated in the notice of proposed revocation that aggregate dietary exposure to residues of carbofuran is "not safe." Carbofuran; Proposed Tolerance Revocations, 73 Fed. Reg. 44,864, 44,865/2 (July 31, 2008) [hereinafter Proposed Revocation]. Specifically, the EPA concluded (1) estimated exposure from food alone, as well as from food and water, "significantly exceed[s] EPA's level of concern for children"; and (2) estimated exposure for both children and adults who receive their drinking water from "vulnerable" sources exceeds the EPA's level of concern. *Id.* at 44,865/3.

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* A dietary risk assessment comprises four steps: (1) identification of the toxicological hazards posed by a pesticide; (2) determination of the "level of concern" for humans; (3) estimation of human exposure to the pesticide; and (4) characterization of risk to humans based upon a comparison between the estimated exposure and the level of concern.

The petitioners submitted extensive Comments in response to the proposed revocation. Also during the comment period, FMC, the only manufacturer of carbofuran in the United States, voluntarily cancelled its registrations under the FIFRA for all but six crops and proposed that the EPA amend the remaining registrations to limit usage in areas particularly susceptible to drinking water contamination (the "First FMC Proposal"), which proposal the EPA accepted, Carbofuran; Product Cancellation Order, 74 Fed. Reg. 11,551 (Mar. 18, 2009).

In May 2009 the EPA issued a Final Regulation revoking all tolerances for carbofuran. Carbofuran; Final Tolerance Revocation, 74 Fed. Reg. 23,046 (May 15, 2009). It concluded that although the First FMC Proposal would reduce exposure to carbofuran, the aggregate exposure from drinking water would still exceed the level of concern with respect to both children and adults. *Id.* at 23,047/3. FMC then proposed another amendment to its registration under the FIFRA, which would further limit carbofuran usage (the "Second FMC Proposal"), and the petitioners filed Objections and a Hearing Request. In November 2009 the EPA denied the petitioners' Objections and Hearing Request. Carbofuran; Order Denying FMC's Objections and Requests for Hearing, 74 Fed. Reg. 59,608 (Nov. 18, 2009) [hereinafter Hearing Denial].** The petitioners seek review of that decision pursuant to 21 U.S.C. § 346(h).

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** Because the merits of the Second FMC Proposal were to be evaluated under the FIFRA rather than the FFDCA, the EPA's order was "not a determination on [those] proposed

## II. Analysis

The petitioners contend they raised four material issues of fact with respect to the revocation of domestic tolerances, each of which merits a hearing: What are the concentrations of carbofuran in (1) surface water and (2) ground water; (3) what is the half-life of carbofuran, which is relevant in determining the extent to which an individual recovers between exposures; and (4) what is the "safe dose" of carbofuran, "*i.e.*, the level below which exposures will not result in adverse effects." Below we conclude the EPA did not abuse its discretion by denying the petitioners' requests for a hearing on the first two issues, which obviates the need to address the second two issues, for they are not by themselves outcome-determinative. The petitioners also contend that, because the EPA agrees the level of exposure to carbofuran from imported foods alone is safe, the agency acted arbitrarily and capriciously by revoking import tolerances. Before reaching any of these arguments, we consider the petitioners' contention that the EPA applied the wrong standard in determining whether an evidentiary hearing was warranted.

### A. Standard for Holding an Evidentiary Hearing

The parties agree the FFDCA and the EPA's regulations establish a "summary-judgment type" standard for determining whether to hold a hearing: The EPA must hold a hearing if it determines an objection raises a material issue of fact. Contrary to the position of the petitioners, however, our review of the EPA's exercise of discretion in determining

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registration amendments." Hearing Denial, 74 Fed. Reg. at 59,609/2.

whether an issue is material differs from our review of a summary judgment rendered by a district court, which we review *de novo*, *Venetian Casino Resort, LLC v. EEOC*, 530 F.3d 925, 929 (D.C.Cir.2008).

The proper standard of review here, as we stated in another case arising under the FFDCA, is "necessarily deferential." *Cmty. Nutrition Inst. v. Young*, 773 F.2d 1356, 1363 (1985).

> Mere differences in the weight or credence given to particular scientific studies, or in the numerical estimates of the average daily intake of [a substance], are insufficient. [We] will not substitute [our] judgment on highly technical and factual matters for that of the agency charged with the supervision of the industry.

*Id.* Rather, our review is "limited to an evaluation of whether [the agency] has given adequate consideration to all relevant evidence in the record." *Id.* at 1362.

**B. Domestic Tolerances**

Having established the standard of review, we turn to the question whether the issues of fact raised by the petitioners are material.

**1. Concentration of carbofuran in surface water**

The petitioners first argue the EPA unrealistically assumed that in any given watershed the percentage of crops treated with carbofuran (PCT) is the legal maximum, *i.e.*, 100%. According to the petitioners, "county-level sales data" show that in no county where carbofuran has been used is the actual PCT higher than 4.25, and this fact is confirmed by data measuring actual carbofuran concentrations in samples of surface water. Finally, they argue the assumption of 100 PCT is "wholly untenable" in light of the Second FMC Proposal, which would purportedly cap the PCT at 2.

The EPA refused to consider any of the documents and arguments the petitioners submitted during the objection stage that they could have but did not submit during the comment stage, holding they were, respectively, untimely and forfeited. The petitioners argue this ruling was inconsistent with the FFDCA and the EPA's own implementing regulations, both of which provide that objections may be filed after promulgation of the Final Regulation and do not explicitly prohibit raising in the objections issues that could have been but were not raised in the comments. The EPA responds that its practice of requiring issues to be raised at the first available opportunity is a reasonable exercise of its broad discretion to "fashion [its] own rules of procedure" in order to implement the multi-stage procedures required by the FFDCA. *Vermont Yankee Nuclear Power Corp. v. NRDC*, 435 U.S. 519, 534-44, 98 S.Ct. 1197, 55 L.Ed.2d 460 (1978); *accord GTE Serv. Corp. v. FCC*, 782 F.2d 263, 274 n. 12 (D.C.Cir.1986). Not only has the agency followed this practice in the past, *e.g.*, Mevinphos; Proposed Amendment and Revocation of Tolerances, 60 Fed. Reg. 39,302, 39,303 (Aug. 2, 1995) ("EPA believes it is appropriate to preclude review of objections raising issues not provided in comments"), but in the Proposed Revocation it specifically reminded parties interested in the present proceeding of the practice, 73 Fed. Reg. at 44,865/2 ("EPA will treat as [forfeited] any issue not originally raised in comments on this proposal").

We agree with the EPA. As the agency points out, the comment period would be redundant and superfluous if the same concerns could be raised at the objection stage. *See FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133, 120 S.Ct. 1291, 146

L.Ed.2d 121 (2000) (statute must be interpreted as a "coherent regulatory scheme" with "all parts [fit] into a harmonious whole"); *APWU, AFL-CIO v. Potter*, 343 F.3d 619, 626 (2d Cir.2003) (statute should be construed "so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant, and so that one section will not destroy another"). Nor would a potentially affected party have an incentive to raise an issue at the comment stage if it could wait without prejudice to see whether doing so was still necessary at the objection stage. *Cf. Pinos-Gonzalez v. Mukasey*, 519 F.3d 436, 440 (8th Cir.2008) (approving of the Board of Immigration Appeals' rule that an issue not raised at the initial hearing before an immigration judge is forfeited for purposes of the administrative appeal). Properly viewed, the objection stage is an opportunity for internal agency review, an opportunity for an interested party to challenge—and for the agency to correct—a matter of fact, law, or policy that appeared for the first time in the Final Regulation, so-called. *Cf. ASARCO, Inc. v. FERC*, 777 F.2d 764, 772 (D.C.Cir.1985) (section 19 of Natural Gas Act, which makes application for agency rehearing a condition of judicial review, "is in part to insure that the [agency] has an opportunity to deal with any difficulties presented by its action *before* the reviewing court intervenes") (internal quotation marks deleted). The EPA's refusal to consider at the objections stage evidence and arguments that could have been but were not submitted during the comment period is also of a piece with the general rule of forfeiture we apply when reviewing agency decisions, *viz.*, that the court will not consider an argument the agency was not given a fair opportunity to consider during the rulemaking. *Nuclear Energy Inst., Inc. v. EPA*, 373 F.3d 1251, 1290

(D.C.Cir.2004); *see also Nat'l Lime Ass'n v. EPA*, 233 F.3d 625, 640-41 (D.C.Cir.2000) (agency need not consider information submitted after the close of the comment period); *USAir, Inc. v. DOT*, 969 F.2d 1256, 1260 (D.C.Cir.1992) (parties "must not be encouraged to 'sandbag' agencies by withholding legal arguments for tactical reasons until they reach the courts of appeal").

The EPA rejected other of the petitioners' arguments at the objection stage on the ground they were "recycled" from the comment stage and had already been addressed when the agency promulgated the Final Regulation. Hearing Denial, 74 Fed. Reg. at 59,658/1. At that time it had rejected the petitioners' arguments concerning the PCT because the petitioners had failed to submit much of the data and the methodology they used to arrive at their estimated PCT of 4.25. Final Regulation, 74 Fed. Reg. at 23,065/1. The agency had also noted in promulgating the Final Regulation that estimates derived from sales data fail to account for the possibility that "use patterns of carbofuran could be concentrated in certain locations, such that a large percentage of a small watershed is treated." *Id.* at 23,066/3. In the order denying the petitioners' Objections and Hearing Request, the EPA concluded that, although "it is unlikely that 100% of the crop will be treated ... in most watersheds," the possibility of 100% treatment, especially in smaller watersheds, meant the agency was "obligat[ed] to evaluate all legally permitted use practices ... and [to] ensure that all such use meets the requisite statutory standards." Hearing Denial, 74 Fed. Reg. at 59,658/3.

We agree with the EPA that the petitioners, by simply resubmitting their Comments, without addressing the responses the EPA had made to them in the Final Regulation, "failed to lodge a relevant objection." *Id.* at 59, 658/1. By statute, an Objection and Hearing Request must be directed "with particularity [to] the provisions of the [final rule] deemed objectionable." 21 U.S.C. § 346a(g)(2); *see also* 40 C.F.R. § 178.25(a)(2). In any event, we "will not substitute [our] judgment on highly technical and factual matters for that of the agency," *Cmty. Nutrition*, 773 F.2d at 1363, and on this record we cannot say the EPA abused its discretion in concluding the petitioners failed to present sufficient evidence to warrant using a PCT lower than 100 when estimating concentrations of carbofuran in surface water.

Finally, the EPA refused to consider any of the petitioners' arguments based upon the Second FMC Proposal. Hearing Denial, 74 Fed. Reg. at 59,658/2. As mentioned in the preceding paragraph, an Objection and Hearing Request must be responsive to the Final Regulation; it must identify some specific error in the regulation. The Second FMC Proposal was submitted to the EPA 44 days after publication of the Final Regulation; Objections that assumed the amendments had been or would be accepted by the agency were not responsive to the Final Regulation, and the EPA properly refused to consider them.

**2. Concentration of carbofuran in groundwater**

The second issue of fact the petitioners claim is material to the Final Regulation concerns the concentration of carbofuran in groundwater. The petitioners' challenges to the EPA's conclusion that concentrations exceed safe levels turns, the parties

agree, upon a single issue of fact, *viz.*, whether carbofuran will be applied in areas with soil that is "vulnerable" to the carbofuran leaching into the groundwater. In their Comments on the proposed revocation the petitioners had relied upon a "National Leaching Assessment" they said was done by a "panel of independent water experts" to demonstrate the geographic restrictions in the First FMC Proposal would ensure against carbofuran being used in areas with vulnerable soils. According to the petitioners, vulnerable areas include only those with

> permeable soils (e.g., areas with soils greater than 90% sand and less than 1% organic matter), acidic soil and water conditions, and [where] shallow water tables predominate (e.g., where groundwater is less than thirty feet).

In the Final Regulation the EPA had noted the petitioners did not submit the National Leaching Assessment itself and said they had failed to explain sufficiently the data and methodologies underlying it. The EPA went on to find the petitioners' criteria for vulnerability were underinclusive, and gave examples of potentially vulnerable areas where carbofuran could still be used if those criteria were adopted. Final Regulation, 74 Fed. Reg. at 23,060/1, 23,078-80. Even taking the First FMC Proposal into account, the EPA had concluded, concentrations of carbofuran in groundwater would not be reduced to "acceptable levels." *Id.* at 23,080/1.

In their Objections and Hearing Request the petitioners restated several arguments they had made in their Comments and argued the Second FMC Proposal would resolve the EPA's remaining doubts about whether carbofuran would be applied to

vulnerable areas. This time they submitted the National Leaching Study for support, as modified to account for the Second FMC Proposal.

The EPA denied the Objections and Hearing Request. As discussed above, it properly refused to consider evidence that could have been but was not submitted with the petitioners' Comments, as well as arguments recycled from earlier Comments and arguments based upon the unapproved Second FMC Proposal. 74 Fed. Reg. at 59653/1, 59654/3-56/1.

On appeal the petitioners characterize the question whether their criteria for "vulnerable" areas are underinclusive as a "dispute between experts," an accurate but a fatal description. As we said in *Community Nutrition*, we will not overturn an agency's finding there is no material issue of fact based upon "[m]ere differences in the weight or credence given to particular scientific studies." 773 F.2d at 1363.

* * *

The petitioners have failed to show a hearing was warranted on either of the first two issues of fact they raised. Therefore, we need not consider the latter two issues; as the petitioners acknowledged at oral argument, resolution in their favor of those two issues alone would not alter the outcome of the administrative proceeding. *See* 40 C.F.R. § 178.32(b)(3) ("An evidentiary hearing will not be granted on factual issues that are not determinative with respect to the outcome requested").

**C. Import Tolerances**

The petitioners contend that even if the EPA properly revoked all domestic tolerances for carbofuran, it acted arbitrarily and capriciously, in

violation of the Administrative Procedure Act, 5 U.S.C. § 706(2)(A), in revoking the import tolerances for carbofuran. The EPA acknowledges that exposure to carbofuran from imported foods alone is safe. The EPA nonetheless revoked all carbofuran tolerances for imported foods, contending the petitioners failed to make a timely request that import tolerances alone be left in effect. Hearing Denial, 74 Fed. Reg. at 59,675/2.

The agency's position is untenable, for the petitioners made such a request on two occasions. First, they included in their Comments five tables representing increasing tolerances they were successively asking the EPA to maintain. One table presented their most modest proposal for retention, showing exposure estimates for "Import Tolerances ... Only." Second, the petitioners expressly stated in a letter to the EPA that they wanted the agency to retain, at minimum, import tolerances "separately, by themselves."*** The EPA's contention the petitioners never asked that import tolerances alone be maintained seems, from what counsel said at oral argument, to be premised upon the idea that a party may not make arguments in the alternative. That is a strange idea, rejection of which requires no display of learning.

In sum, the petitioners asked that if all else failed, the import tolerances for carbofuran should be maintained because the EPA itself considered them

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*** The letter was submitted after the close of the comment period but the EPA did not suggest until oral argument that the letter was untimely. *See BNSF Ry. Co. v. STB*, 604 F.3d 602, 611 (D.C.Cir.2010) ("a forfeiture can be forfeited by failing on appeal to argue an argument was forfeited"); *Ark Las Vegas Rest. Corp. v. NLRB*, 334 F.3d 99, 108 n. 4 (D.C.Cir.2003) (argument raised for first time at oral argument is forfeited).

safe. The EPA's decision to revoke those tolerances was arbitrary and capricious.

## III. Conclusion

We grant the petition for review in part and vacate the EPA's final rule to the extent it revoked the import tolerances for carbofuran. We deny the petition for review in all other respects.

*So ordered.*

74 Fed. Reg. 59,608
Wednesday, November 18, 2009

ENVIRONMENTAL PROTECTION AGENCY

**40 CFR Part 180**

**[EPA-HQ-OPP-2005-0162; FRL-8797-6]**

**Carbofuran; Order Denying FMC's Objections and Requests for Hearing**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Order.

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**SUMMARY:** In this order, EPA denies objections to, and requests for hearing on, a final rule revoking all pesticide tolerances for carbofuran under section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA). The objections and hearing requests were filed on June 30, 2009, by the National Corn Growers Association, National Sunflower Association, National Potato Council, and FMC Corporation ("Petitioners").

**DATES:** This final order is effective November 18, 2009.

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2005-0162. To access the electronic docket, go to *http://www.regulations.gov*, and search for the docket number. Follow the instructions on the regulations.gov Web site to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, *e.g.*, Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not

placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:** Jude Andreasen, Pesticide Re-evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-9342; e-mail address: *andreasen.jude@epa.gov*.

**SUPPLEMENTARY INFORMATION:**

## I. General Information

### *A. Does this Action Apply to Me?*

In this document EPA denies objections and hearing requests by the National Corn Growers Association, National Sunflower Association, National Potato Council, and FMC Corporation ("Petitioners") concerning EPA's final rule revoking all pesticide tolerances for carbofuran. This action may also be of interest to agricultural producers, food manufacturers, or pesticide manufacturers. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under FOR FURTHER INFORMATION CONTACT.

*B. How Can I Access Electronic Copies of this Document?*

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the **Federal Register** listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*.

*C. Acronyms*

The following is a list of acronyms used in this order:

AChE—Acetylcholinesterase

aPAD—Acute Population Adjusted Dose

BMD—Bench Mark Dose

BMDL—Bench Mark Dose Level

CCA—Comparative Cholinesterase Assay

CNS—Central Nervous System

CRA—Cumulative Risk Assessment

CSFII—Continuing Survey of Food Intakes by Individuals

CWA—Clean Water Act

CWS—Community Water System

DEEM–FCID—Dietary Exposure Evaluation Model-Food Commodity Intake Database

ECG—Electrocardiogram

EDWC—Estimated Drinking Water Concentration

EPA—Environmental Protection Agency

FACA—Federal Advisory Committee Act

FDA—Food and Drug Administration

FIFRA—Federal Insecticide, Fungicide, and Rodenticide Act

FFDCA—Federal Food, Drug, and Cosmetic Act

FQPA—Food Quality Protection Act of 1996

HSRB—Human Studies Review Board

HUC—8—8-digit hydrologic unit code

IRED—Interim Reregistration Eligibility Decision

$LD_{50}$—Lethal Dose for 50% of a population

LOAEL—Lowest Observable Adverse Effect Level

NAWQA—National Water Quality Assessment Program

NHEERL—National Health and Environmental Effects Laboratory

NMC CRA—N-Methyl Carbamate Cumulative Risk Assessment

NOAEL—No Observable Adverse Effect Level

NOIC—Notice of Intent to Cancel

NRDC—National Resources Defense Council

OP—Organophosphate

ORD—Office of Research and Development

PAD—Population Adjusted Dose
PCA—Percent Cropped Area
PCT—Percent Crop Treated
PDP—Pesticide Data Program
PND—Post-Natal Day
PNS—Peripheral Nervous System
PoD—Point of Departure
ppb—parts per billion
ppm—parts per million
PRZM-EXAMS—Pesticide Root Zone Model-Exposure Analysis Model System
RBC—red blood cell
RED—Reregistration Eligibility Decision
RfD—Reference Dose
SAP—Scientific Advisory Panel
SDWA—Safe Drinking Water Act
USDA—United States Department of Agriculture
USGS—United States Geological Survey
WARP—Watershed Regression for Pesticides

## II. Introduction

### *A. What Action Is the Agency Taking?*

Exposure to the pesticide carbofuran resulting from existing legal uses is unsafe—unsafe for the general population, and particularly unsafe for infants and children. EPA reached this conclusion in 2006 after an exhaustive multi-year review of the data on carbofuran as part of its effort to determine whether carbofuran should be reregistered under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), and whether the tolerances allowing carbofuran residues on certain foods met the revised safety standard in section 408 of the FFDCA. This multi-year review

included multiple opportunities for public participation, including no less than four formal public comment periods. Following EPA review of yet more carbofuran data submitted by FMC, the carbofuran registrant, and the review of EPA's science findings by the FIFRA Scientific Advisory Panel (SAP)—an independent scientific peer review panel—EPA again reached the same conclusion in its July 31, 2008 proposal to revoke the carbofuran tolerances (73 FR 44864 (July 31, 2008)). In response to this proposed revocation, FMC submitted comments challenging many of EPA's science findings and also requesting the cancellation of the registration of carbofuran on several crops and the restriction of where, and the manner in which, carbofuran could be used in the United States on its remaining registered crop sites. Finding FMC's science arguments to be flawed and its proposed amendments to the carbofuran registration to be insufficient, EPA finalized the rule revoking carbofuran tolerances on May 15, 2009 (74 FR 23046 (May 15, 2009)).

Pursuant to the procedures of the FFDCA, on June 29, 2009 objections to the final revocation rule were filed by the National Corn Growers Association, National Sunflower Association, National Potato Council, and FMC Corporation ("Petitioners"). The Petitioners also requested a hearing on their objections. Coupled with these objections, FMC filed on the same day yet another series of proposed amendments to its carbofuran registration. These proposed modifications contained new application and geographic restrictions as well as an unprecedented non-governmental scheme for preventing the use of carbofuran in any one area of the country above a small

percentage of that area's agricultural acreage. The Petitioners relied on these proposed carbofuran registration amendments as central to, and inextricably intertwined with, their objection to EPA's prior determination in the final rule that carbofuran tolerances are unsafe. Specific challenges raised by the Petitioners involved EPA's decision on the appropriate level of the additional safety factor to protect infants and children, EPA's estimate of carbofuran levels in drinking water, EPA's consideration of the time needed to recover from exposure to carbofuran, and EPA's refusal to consider a human toxicity study conducted with carbofuran.

Today's order denies all of the Petitioners' objections and requests for hearing. A principal flaw in the Petitioners' objections is that they have objected to EPA's determination in the final rule on the safety of carbofuran based on the FIFRA registration amendments that FMC filed with EPA 45 days after the safety determination was made. As such, the Petitioners' objections are irrelevant, and thus immaterial, to the determination EPA made in the final rule. FMC has the statutory right under FIFRA to request amendment of its carbofuran registration. What Petitioners may not do is prolong the FFDCA tolerance revocation process by challenging EPA's safety determination based on proposed FIFRA registration changes not before EPA at the time of its final revocation decision.

It should be noted that EPA's decision on the carbofuran tolerances is not a determination on FMC's proposed registration amendments. FMC may continue to pursue these amendments and also the re-establishment of carbofuran tolerances in light of the

amendments. Further, FMC may seek administrative review, and potentially an administrative hearing, with regard to any adverse decision issued by EPA on its proposed amendments. But that process must be played out in the future, a future in which any decision about the safety of carbofuran is made prior to the re-introduction of carbofuran residues in food and water, rather than concurrent with the continued exposure of infants and children to levels of carbofuran residues that EPA has found to be unsafe.

Despite the fact that a central aspect of the Petitioners' objections is based on a flawed conception of the objection process (*i.e.*, the notion that the objection process presents the opportunity for a complete reformulation of the matter in dispute, rather than a chance for a review of the accuracy of EPA's earlier determination), EPA has undertaken a comprehensive analysis of the merits of each of the Petitioners' objections and hearing requests. That analysis shows, as is exhaustively set out in Unit VI, that none of the Petitioners' requests for hearing meets the regulatory standard for granting a hearing and none of the Petitioners' objections has merit. There are numerous reasons for these conclusions, but two related themes running throughout EPA's analysis are the Petitioners' failure to timely raise issues or submit supporting documents during the public comment process on the proposed rule and the Petitioners' failure to object to how EPA, in the final rule, resolved the issues the Petitioners did raise in the comment process. EPA considers issues untimely raised to be waived—as EPA clearly warned at the proposal stage—and finds recycled comments on the proposed rule to be irrelevant to the detailed determinations

made in the final rule. The rulemaking phase of the revocation process has a purpose, and parties treat it lightly at their peril. Finally, EPA notes that an additional problem with the Petitioners' objections is that once the newly proposed registration amendments are stripped from the objections, it is not at all clear that any remaining issues, even if concluded in the Petitioners' favor, would result in lowering carbofuran's estimated risks—which EPA has estimated as far exceeding the safety standard—to an acceptable level. For all of these reasons, the Petitioners' objections and hearing requests are denied.

*B. What Is the Agency's Authority for Taking This Action?*

EPA is taking this action pursuant to the authority in FFDCA section 408(g)(2)(C), which requires the Agency to issue a final order resolving the objections to its final rule, issued pursuant to 408(b)(1)(b), 408(b)(2)(A), and 408(e)(1)(A). 21 U.S.C. 346a(b)(1)(b), (b)(2)(A), (e)(1)(A), (g)(2)(C).)

## III. Statutory and Regulatory Background

In this Unit, EPA provides background on the relevant statutes and regulations governing the Petitioners' objections and requests for hearing as well as on pertinent Agency policies and practices.

*A. FFDCA/FIFRA and Applicable Regulations*

1. *In general.* EPA establishes maximum residue limits, or "tolerances," for pesticide residues in food under section 408 of the FFDCA (21 U.S.C. 346a). Without such a tolerance or an exemption from the requirement of a tolerance, a food containing a pesticide residue is "adulterated" under section 402 of the FFDCA and may not be legally moved in interstate

commerce (21 U.S.C. 331, 342). Monitoring and enforcement of pesticide tolerances are carried out by the U.S. Food and Drug Administration ("FDA") and the U.S. Department of Agriculture ("USDA"). Section 408 was substantially rewritten by the Food Quality Protection Act of 1996 ("FQPA"), which added the provisions discussed below establishing a detailed safety standard for pesticides, additional protections for infants and children, and the process for establishing or revoking tolerances (Pub. L. 104-170, 110 Stat. 1489 (1996)).

EPA also regulates pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") (7 U.S.C. 136 *et seq.*). While the FFDCA authorizes the establishment of legal limits for pesticide residues in food, FIFRA requires the approval of pesticides prior to their sale and distribution (7 U.S.C. 136a(a)), and establishes a registration regime for regulating the use of pesticides. FIFRA regulates pesticide use in conjunction with its registration scheme by requiring EPA review and approval of pesticide labels and specifying that use of a pesticide inconsistent with its label is a violation of federal law (7 U.S.C. 136j(a)(2)(G)). In the FQPA, Congress integrated action under the two statutes by requiring that the safety standard under the FFDCA be used as a criterion in FIFRA registration actions as to pesticide uses that result in dietary risk from residues in or on food (7 U.S.C. 136(bb)), and directing that EPA coordinate, to the extent practicable, revocations of tolerances with pesticide cancellations under FIFRA. (21 U.S.C. 346a(l)(1)).

2. *Safety standard for pesticide tolerances.* Section 408(b)(2)(A)(i) of the FFDCA requires EPA to

modify or revoke a tolerance if EPA determines that the tolerance is not "safe" (21 U.S.C. 346a(b)(2)(A)(ii)). Section 408(b)(2)(A)(ii) of the FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(D) directs EPA, in making a safety determination, to:

> Consider, among other relevant factors—* * *
>
> (vi) Available information concerning the aggregate exposure levels of consumers (and major identifiable subgroups of consumers) to the pesticide chemical residue and to other related substances, including dietary exposure under the tolerance and all other tolerances in effect for the pesticide chemical residue, and exposure from other non-occupational sources;

EPA must also consider, in evaluating the safety of tolerances, "safety factors which * * * are generally recognized as appropriate for the use of animal experimentation data." (21 U.S.C. 346a(b)(2)(D)(ix).)

Risks to infants and children are given special consideration. Specifically, section 408(b)(2)(C) states that EPA:

> Shall assess the risk of the pesticide chemical based on—* * *
>
> (II) Available information concerning the special susceptibility of infants and children to the pesticide chemical residues, including neurological differences between infants and children and adults, and effects of in utero exposure to pesticide chemicals;

(21 U.S.C. 346a(b)(2)(C)(i)(II) and (III)). This provision also creates a presumptive additional safety factor for the protection of infants and children. Specifically, it directs that "[i]n the case of threshold effects, * * * an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children" (21 U.S.C. 346a(b)(2)(C)). EPA is permitted to "use a different margin of safety for the pesticide chemical residue only if, on the basis of reliable data, such margin will be safe for infants and children" (Id.). The additional safety margin for infants and children is referred to throughout this order as the "children's safety factor."

3. *Procedures for establishing, amending, or revoking tolerances.* Tolerances are revoked by rulemaking under the unique procedural framework set forth in the FFDCA. Section 408(e) of the FFDCA, 21 U.S.C. 346a(e), authorizes EPA to modify or revoke tolerances on its own initiative.

In issuing a regulation on its own initiative, EPA must first publish a notice of proposed rulemaking, and must generally provide at least 60 days to allow the public to comment on the proposed regulation. After considering comments submitted during this comment period, EPA issues a final rule.

Once EPA issues a final rule, any person may file objections with EPA and, if desired, request an evidentiary hearing on those objections (21 U.S.C. 346a(g)(2)). Objections must specify "with particularity the provisions of the regulation * * * deemed objectionable and stating reasonable grounds therefore" (21 U.S.C. 346a(g)(2)(A); 40 CFR 178.25(a)).

Objections and hearing requests must be filed within 60 days (Id.). The statute provides that EPA shall "hold a public evidentiary hearing if and to the extent the Administrator determines that such a public hearing is necessary to receive factual evidence relevant to material issues of fact raised by the objections" (21 U.S.C. 346a(g)(2)(B)). EPA regulations make clear that hearings will only be granted where it is shown that there is "a genuine and substantial issue of fact;" the requestor has identified evidence "which, if established, will resolve one or more of such issues in favor of the requestor," and the issue is "determinative" with regard to the relief requested (40 CFR 178.32(b)). After consideration of any objections, EPA must issue a final order stating the action taken in response to each objection, including a determination as to whether any hearing is appropriate (21 U.S.C. 346a(g)(2)(C)). The final order also establishes any revisions to the final regulation EPA deems to be warranted based on the objections. Id. EPA's final order on the objections is subject to judicial review in the Court of Appeals, within 60 days of the publication of the order (21 U.S.C. 346a(h)(1)).

4. *Tolerance reassessment and FIFRA reregistration.* EPA revoked the carbfuran tolerances to implement the Agency's findings made during the reregistration and tolerance reassessment processes.

The FQPA required that EPA reassess the safety of all pesticide tolerances existing at the time of its enactment. (21 U.S.C. 346a(q)). EPA was given 10 years to reassess the approximately 10,000 tolerances in existence in 1996. In this reassessment, EPA was required to review existing pesticide tolerances under the new "reasonable certainty that no harm will result"

standard set forth in section 408(b)(2)(A)(i). (21 U.S.C. 346a(b)(2)(A)(i)). This reassessment was substantially completed by the August 3, 2006 deadline. Tolerance reassessment was generally handled in conjunction with a similar program involving reregistration of pesticides under FIFRA. (7 U.S.C. 136a-1). Reassessment and reregistration decisions were generally combined in a document labeled a Reregistration Eligibility Decision (RED).

*B. EPA's Human Research Rule*

EPA decisions regarding the use of human studies in pesticide regulatory decisions are governed by the Protection for Subjects in Human Research final rule ("Human Research rule"), which significantly strengthened and expanded protections for subjects of human research (71 FR 6138 (February 6, 2006)). The framework of the Human Research rule rests on the basic principle that EPA will not, in its actions, rely on data derived from unethical research. The rule divides studies involving intentional dosing of human subjects into two groups: "new" studies-those initiated after April 7, 2006 (the effective date of the rule)-and "old" studies-those initiated before April 7, 2006. The Human Research Rule forbids EPA from relying on data from any "new" study, unless EPA has adequate information to determine that the research was conducted in substantial compliance with the ethical requirements contained therein (40 CFR 26.1705). These ethical rules are derived primarily from the "Common Rule," (40 CFR part 26), a rule setting ethical parameters for studies conducted or supported by the federal government. In addition to requiring informed consent and protection of the safety of the subjects, among other things, the rule specifies that

"[r]isks to subjects [must be] reasonable in relation to * * * the importance of the knowledge that may reasonably be expected to result [from the study]." (40 CFR 26.1111(a)(2)). In other words, a study would be judged unethical if it did not have scientific value outweighing any risks to the test subjects.

As to "old" studies, the Human Research Rule forbids EPA from relying on such data if there is clear and convincing evidence that the conduct of the research was fundamentally unethical or significantly deficient with respect to the ethical standards prevailing at the time the research was conducted (40 CFR 26.1704). EPA has indicated that in evaluating "the ethical standards prevailing at the time the research was conducted" it will consider the Nuremburg Code, various editions of the Declaration of Helsinki, the Belmont Report, and the Common Rule, as among the standards that may be applicable to any particular study (71 FR at 6161). Further, reflecting the concern that scientifically invalid data are "always unethical," (71 FR at 6160), the rule limits the human research that can be relied upon by EPA to "scientifically valid and relevant data" (40 CFR 26.1701).

Whether the data are "new" or "old," the Human Research rule forbids EPA from relying on data from any study involving intentional exposure of pregnant women, fetuses, or children subject to a very limited exception (40 CFR 26.1703, 1706).

To aid EPA in making scientific and ethical determinations under the Human Research rule, the rule established an independent Human Studies Review Board (HSRB) to review both proposals for new research (new studies) and reports of completed

human research (old studies) on which EPA proposes to rely (40 CFR 26.1603). The rule directs that the HSRB shall be comprised of non-EPA employees "who have expertise in fields appropriate for the scientific and ethical review of human research, including research ethics, biostatistics, and human toxicology" (40 CFR 26.1603(a)). If EPA decides to rely on the results from "old" research conducted to identify or measure a toxic effect, EPA must submit the results of its assessment to the HSRB for evaluation of the ethical and scientific merit of the research (40 CFR 26.1602(b)(2)).

EPA has established the HSRB as a federal advisory committee under the Federal Advisory Committee Act (FACA) to take advantage of "the benefits of the transparency and opportunities for public participation" that accompany a FACA committee (71 FR at 6156). The HSRB, as appointed by EPA, contains approximately 16 distinguished experts in the fields of bioethics, biostatistics, human health risk assessment and human toxicology, primarily from academia (Ref. 10).

## IV. EPA's Approach to Dietary Risk Assessment

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. A short summary is provided below to aid the reader. For further discussion of the regulatory requirements of section 408 of the FFDCA and a complete description of the risk assessment process, see *http://www.epa.gov/fedrgstr/EPA-PEST/1999/January/Day-04/p34736.htm.*

To assess the risk of a pesticide tolerance, EPA combines information on pesticide toxicity with information regarding the route, magnitude, and

duration of exposure to the pesticide. The risk assessment process involves four distinct steps: (1) Identification of the toxicological hazards posed by a pesticide; (2) determination of the exposure "level of concern" for humans; (3) estimation of human exposure; and (4) characterization of human risk based on comparison of human exposure to the level of concern.

*A. Hazard Identification and Selection of Toxicological Endpoint*

1. In General. Any risk assessment begins with an evaluation of a chemical's inherent properties, and whether those properties have the potential to cause adverse effects (i.e., hazard identification). EPA then evaluates the hazards to determine the most sensitive and appropriate adverse effect of concern, based on factors such as the effect's relevance to humans and the likely routes of exposure.

Once a pesticide's potential hazards are identified, EPA determines a toxicological level of concern for evaluating the risk posed by human exposure to the pesticide. In this step of the risk assessment process, EPA essentially evaluates the levels of exposure to the pesticide at which effects might occur. An important aspect of this determination is assessing the relationship between exposure (dose) and response (often referred to as the dose-response analysis). In evaluating a chemical's dietary risks EPA uses a reference dose (RfD) approach, which involves a number of considerations including:

- A 'point of departure' (PoD)-the value from a dose-response curve that is at the low end of the observable data and that is the dose that serves as the 'starting point' in extrapolating a risk to the human population;

- An uncertainty factor to address the potential for a difference in toxic response between humans and animals used in toxicity tests (*i.e.*, interspecies extrapolation);
- An uncertainty factor to address the potential for differences in sensitivity in the toxic response across the human population (*i.e.*, intraspecies variability); and
- The need for an additional safety factor to protect infants and children, as specified in FFDCA section 408(b)(2)(C).

EPA uses the chosen PoD to calculate a safe dose or RfD. The RfD is calculated by dividing the chosen PoD by all applicable safety or uncertainty factors. Typically in EPA risk assessments, a combination of safety or uncertainty factors providing at least a hundredfold (100X) margin of safety is used: 10X to account for interspecies extrapolation and 10X to account for intraspecies variability. Further, as required by FFDCA section 408(b)(2)(C), in evaluating the dietary risks for pesticide chemicals, an additional safety factor of 10X is presumptively applied to protect infants and children, unless reliable data support selection of a different factor. In implementing FFDCA section 408, EPA also calculates a variant of the RfD referred to as a Population Adjusted Dose (PAD). A PAD is the RfD divided by any portion of the children's safety factor that does not correspond to one of the traditional additional uncertainty/safety factors used in general Agency risk assessment. The reason for calculating PADs is so that other parts of the Agency, which are not governed by FFDCA section 408, can, when evaluating the same or similar substances, easily identify which aspects of a pesticide

risk assessment are a function of the particular statutory commands in FFDCA section 408. For acute assessments, the risk is expressed as a percentage of a maximum acceptable dose or the acute PAD (*i.e.*, the acute dose which EPA has concluded will be "safe"). As discussed below in Unit V.C., dietary exposures greater than 100 percent of the acute PAD are generally cause for concern and would be considered "unsafe" within the meaning of FFDCA section 408(b)(2)(B). Throughout this document general references to EPA's calculated safe dose are denoted as an acute PAD, or aPAD, because the relevant point of departure for carbofuran is based on an acute risk endpoint.

*2. Acetylcholinesterase Inhibition.* Carbofuran is a member of the class of pesticides called N-methyl carbamates (NMCs). The primary toxic effect caused by NMCs, including carbofuran, is neurotoxicity resulting from inhibition of the enzyme acetylcholinesterase (AChE). The toxicity profile of these pesticides is characterized by rapid time to onset of effects followed by rapid recovery (minutes to hours). Consistent with its mechanism of action, toxicity data on AChE inhibition from laboratory rats provide the basis for deriving the PoD for carbofuran.

AChE inhibition is a disruption of the normal process in the body by which the nervous system chemically communicates with muscles and glands. Communication between nerve cells and a target cell (*i.e.*, another nerve cell, a muscle fiber, or a gland) is facilitated by the chemical, acetylcholine. When a nerve cell is stimulated it releases acetylcholine into the synapse (or space) between the nerve cell and the target cell. The released acetylcholine binds to

receptors in the target cell, stimulating the target cell in turn. As EPA has explained, "the end result of the stimulation of cholinergic pathway(s) includes, for example, the contraction of smooth (*e.g.*, in the gastrointestinal tract) or skeletal muscle, changes in heart rate or glandular secretion (*e.g.*, sweat glands) or communication between nerve cells in the brain or in the autonomic ganglia of the peripheral nervous system." (Ref. 78 at 10).

AChE is an enzyme that breaks down acetylcholine and terminates its stimulating action in the synapse between nerve cells and target cells. When AChE is inhibited, acetylcholine builds up prolonging the stimulation of the target cell. This excessive stimulation potentially results in a broad range of adverse effects on many bodily functions including muscle cramping or paralysis, excessive glandular secretions, or effects on learning, memory, or other behavioral parameters. Depending on the degree of inhibition these effects can be serious, even fatal.

EPA's cholinesterase inhibition policy statement explains EPA's approach to evaluating the risks posed by AChE-inhibiting pesticides such as carbofuran (Ref. 78 at 10). The policy focuses on three types of effects associated with AChE-inhibiting pesticides that may be assessed in animal and human toxicological studies: (1) Physiological and behavioral/functional effects; (2) AChE inhibition in the central and peripheral nervous system; and (3) AChE inhibition in red blood cells and blood plasma. The policy discusses how such data should be integrated in deriving an acceptable dose (RfD/PAD) for a AChE-inhibiting pesticide.

After clinical signs or symptoms, AChE inhibition in the nervous system provides the next most important endpoint for evaluating AChE-inhibiting pesticides. Although AChE inhibition in the nervous system is not itself regarded as a direct adverse effect, it is "generally accepted as a key component of the mechanism of toxicity leading to adverse cholinergic effects" (Id. at 25). As such, the policy states that it should be treated as "direct evidence of potential adverse effects" and "data showing this response provide valuable information in assessing potential hazards posed by antiAChE pesticides" (Id.). Unfortunately, useful data measuring AChE inhibition in the peripheral nervous system tissues has only been relatively rarely captured by standard toxicology testing, particularly for the NMC compounds. For central nervous system effects, however, more recent neurotoxicity studies "have sought to characterize the time course of inhibition in * * * [the] brain, including brain regions, after acute and 90-day exposures" (Id. at 27).

AChE inhibition in the blood is one step further removed from the direct harmful consequences of AChE-inhibiting pesticides. According to the policy, inhibition of blood AChEs "is not an adverse effect, but may indicate a potential for adverse effects on the nervous system" (Id. at 28). The policy states that "[a]s a matter of science policy, blood AChE data are considered appropriate surrogate measures of potential effects on peripheral nervous system AChE activity in animals, for central nervous system ("CNS") AChE activity in animals when CNS data are lacking and for both peripheral and central nervous system AChE in humans" (Id. at 29). The policy notes that "there is

often a direct relationship between a greater magnitude of exposure [to a AChE-inhibiting pesticide] and an increase in incidence and severity of clinical signs and symptoms as well as blood AChE inhibition" (Id. at 30). Thus, the policy regards blood AChE data as "appropriate endpoints for derivation of reference doses or concentrations when considered in a weight-of-the-evidence analysis of the entire database * * *" (Id. at 29). Between AChE inhibition measured in red blood cell ("RBC") or blood plasma, the policy states a preference for reliance on RBC AChE measurements because plasma is composed of a mixture of acetylcholinesterase and butyrylcholinesterase, and inhibition of the latter is less clearly tied to inhibition of acetylcholinesterase in the nervous system (Id. at 29, 32).

EPA has relied on a benchmark dose (BMD) approach for deriving the PoD from the available rat toxicity studies. A BMD is a point estimate along a dose-response curve that corresponds to a specific response level. For example, a $BMD_{10}$ represents a 10% change from the background; 10% is often used as a typical value for the response of concern (Ref. 76). Generically, the direction of change from background can be an increase or a decrease depending on the biological parameter and the chemical of interest. In the case of carbofuran, inhibition of AChE is the toxic effect of concern. Following exposure to carbofuran, the normal biological activity of the AChE enzyme is decreased (*i.e.*, the enzyme is inhibited). Thus, when evaluating BMDs for carbofuran, the Agency is interested in a decrease in AChE activity compared to normal activity levels, which are also termed "background" levels. Measurements of "background"

AChE activity levels are usually obtained from animals in experimental studies that are not treated with the pesticide of interest (*i.e.*, "negative control" animals).

In addition to the BMD, a confidence limit was also calculated. Confidence limits express the uncertainty in a BMD that may be due to sampling and/or experimental error. The lower confidence limit on the dose used as the BMD is termed the BMDL, which the Agency uses as the PoD. Use of the BMDL for deriving the PoD rewards better experimental design and procedures that provide more precise estimates of the BMD, resulting in tighter confidence intervals. Use of the BMDL also helps ensure with high confidence (*e.g.*, 95% confidence) that the selected percentage of AChE inhibition is not exceeded. From the PoD, EPA calculates the RfD and aPAD. Specific to carbofuran and the other NMCs, EPA the FIFRA SAP has reviewed and supported the statistical methods used to derive the BMD and BMDLs on multiple occasions (Refs. 34, 35, 36).

In the Agency's BMD analysis for carbofuran, EPA used a response level of 10% brain AChE inhibition; this value represents the estimated dose where AChE is inhibited by 10%, compared to untreated animals. For the last several years EPA has used the 10% value to regulate AChE inhibiting pesticides, including organophosphorous pesticides (OPs) and NMCs. For a variety of toxicological and statistical reasons, EPA chose 10% brain AChE inhibition as the response level for use in BMD calculations. EPA analyses have demonstrated that 10% is a level that can be reliably measured in the majority of rat toxicity studies; is generally at or near the limit of sensitivity for discerning a statistically significant decrease in AChE

activity across the brain compartment; and is a response level close to the background (Refs. 34, 35).

*B. Estimating Human Dietary Exposure Levels*

Pursuant to section 408(b) of the FFDCA, EPA has evaluated carbofuran's dietary risks based on "aggregate exposure" to carbofuran. By "aggregate exposure," EPA is referring to exposure to carbofuran by multiple pathways of exposure. EPA uses available data and standard analytical methods, together with assumptions designed to be protective of public health, to produce separate estimates of exposure for a highly exposed subgroup of the general population, for each potential pathway and route of exposure. For acute risks, EPA then calculates potential aggregate exposure and risk by using probabalistic[1] techniques to combine distributions of potential exposures in the population for each route or pathway. For dietary analyses, the relevant sources of potential exposure to carbofuran are from the ingestion of residues in food and drinking water. The Agency uses a combination of monitoring data and predictive models to evaluate environmental exposure of humans to carbofuran.

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[1] Probabilistic analysis is used to predict the frequency with which variations of a given event will occur. By taking into account the actual distribution of possible consumption and pesticide residue values, probabilistic analysis for pesticide exposure assessments "provides more accurate information on the range and probability of possible exposure and their associated risk values" (Ref. 77). In capsule, a probabilistic pesticide exposure analysis constructs a distribution of potential exposures based on data on consumption patterns and residue levels and provides a ranking of the probability that each potential exposure will occur. People consume differing amounts of the same foods, including none at all, and a food will contain differing amounts of a pesticide residue, including none at all.

1. *Exposure from Food.* The level of human exposure to pesticide residues in food is a function of both the pesticide residues in food and the amount of food consumed. Data on the residues of carbofuran in foods are available from a variety of sources. One of the primary sources of data comes from federally-conducted surveys, including the Pesticide Data Program (PDP) conducted by the USDA. Further, market basket surveys, which are typically performed by registrants, can provide additional residue data. These data generally provide a characterization of pesticide residues in or on foods consumed by the U.S. population that closely approximates real world exposures because they are sampled closer to the point of consumption in the chain of commerce than field trial data, which are generated to establish the maximum level of legal residues that could result from maximum permissible use of the pesticide. In certain circumstances, when EPA believes the information will provide more accurate exposure estimates, EPA will rely on field trial data (see below in Unit VI.E.1).

EPA relies on USDA's Continuing Survey of Food Intake by Individuals (CSFII) for information on food consumption by the US population as well as 32 subgroups based on age, gender, ethnicity, and region. The latest CSFII was conducted in 1994-1996 and 1998. The 1998 survey was a special survey required by the FQPA to supplement the number of children survey participants. DEEM-FCID also contains "recipes" that convert foods as consumed (*e.g.*, pizza) back into their component raw agricultural commodities (*e.g.*, wheat from flour, or tomatoes from sauce, etc.). This is necessary because residue data are generally gathered on raw agricultural commodities rather than on

finished ready-to-eat food. Data on residue values for a particular pesticide and the RfD or PADs for that pesticide are inputs to the DEEM-FCID computer program to estimate exposure and risk.

The DEEM-FCID computer program estimates exposure by combining data on human consumption amounts with residue values in food commodities. DEEM-FCID also compares exposure estimates to appropriate RfD or PAD values to estimate risk. EPA uses DEEM-FCID to estimate exposure for the general U.S. population as well as for 32 subgroups based on age, sex, ethnicity, and region. DEEM-FCID allows EPA to process extensive volumes of data on human consumption amounts and residue levels in making risk estimates. Matching consumption and residue data, as well as managing the thousands of repeated analyses of the consumption database conducted under probabilistic risk assessment techniques, requires the use of a computer.

For carbofuran's assessment, EPA used DEEM-FCID to calculate risk estimates based on a probabilistic distribution. DEEM-FCID combines the full range of residue values for each food with the full range of data on individual consumption amounts to create a distribution of exposure and risk levels. More specifically, DEEM-FCID creates this distribution by calculating an exposure value for each reported day of consumption per person ("person/day") in CSFII, assuming that all foods potentially bearing the pesticide residue contain such residue at a value selected randomly from the exposure data sets. The exposure amounts for the thousands of person/days in the CSFII are then collected in a frequency distribution. EPA also uses DEEM-FCID to compute

a distribution taking into account both the full range of data on consumption levels and the full range of data on potential residue levels in food. Combining consumption and residue levels into a distribution of potential exposures and risk requires use of probabilistic techniques.

The probabilistic technique that DEEM-FCID uses to combine differing levels of consumption and residues involves the following steps:

(1) Identification of any food(s) that could bear the residue in question for each person/day in the CSFII;

(2) Calculation of an exposure level for each of the thousands of person/days in the CSFII database, based on the foods identified in Step #1 by randomly selecting residue values for the foods from the residue database;

(3) Repetition of Step #2 one thousand times for each person/day; and

(4) Collection of all of the hundreds of thousands of potential exposures estimated in Steps 2 and 3 in a frequency distribution.

The resulting probabilistic assessment presents a range of exposure/risk estimates.

2. *Exposure from water.* EPA may use field monitoring data and/or simulation water exposure models to generate pesticide concentration estimates in drinking water. Monitoring and modeling are both important tools for estimating pesticide concentrations in water and can provide different types of information. Monitoring data can provide estimates of pesticide concentrations in water that are representative of the specific agricultural or residential pesticide practices in specific locations, under the environmental conditions associated with a sampling design (*i.e.*, the locations of sampling, the times of the year samples were taken,

and the frequency by which samples were collected). Although monitoring data can provide a direct measure of the concentration of a pesticide in water, it does not always provide a reliable basis for estimating spatial and temporal variability in exposures because sampling may not occur in areas with the highest pesticide use, and/or when the pesticides are being used and/or at an appropriate sampling frequency to detect high concentrations of a pesticide that occur over the period of a day to several days.

Because of the limitations in most monitoring studies, EPA's standard approach is to use simulation water exposure models as the primary means to estimate pesticide exposure levels in drinking water. Modeling is a useful tool for characterizing vulnerable sites, and can be used to estimate peak pesticide water concentrations from infrequent, large rain events. EPA's computer models use detailed information on soil properties, crop characteristics, and weather patterns to estimate water concentrations in vulnerable locations where the pesticide could be used according to its label (69 FR 30042, 30058-30065 (May 26, 2004)). These models calculate estimated water concentrations of pesticides using laboratory data that describe how fast the pesticide breaks down to other chemicals and how it moves in the environment at these vulnerable locations. The modeling provides an estimate of pesticide concentrations in ground and surface water. Depending on the modeling algorithm (*e.g.*, surface water modeling scenarios), daily concentrations can be estimated continuously over long periods of time, and for places that are of most interest for any particular pesticide.

EPA relies on models it has developed for estimating pesticide concentrations in both surface water and ground water. Typically EPA uses a two-tiered approach to modeling pesticide concentrations in surface and ground water. If the first tier model suggests that pesticide levels in water may be unacceptably high, a more refined model is used as a second tier assessment. The second tier model for surface water is actually a combination of two models: The Pesticide Root Zone Model (PRZM) and the Exposure Analysis Model System (EXAMS). The second tier model for ground water uses PRZM alone.

A detailed description of the models routinely used for exposure assessment is available from the EPA OPP Water Models Web site: *http://www.epa.gov/oppefed1/models/water/index.htm.* These models provide a means for EPA to estimate daily pesticide concentrations in surface water sources of drinking water (a reservoir) using local soil, site, hydrology, and weather characteristics along with pesticide application and agricultural management practices, and pesticide environmental fate and transport properties. Consistent with the recommendations of the FIFRA SAP, EPA also considers regional percent cropped area factors (PCA) which take into account the potential extent of cropped areas that could be treated with pesticides in a particular area. The PRZM and EXAMS models used by EPA were developed by EPA's Office of Research and Development (ORD), and are used by many international pesticide regulatory agencies to estimate pesticide exposure in surface water. EPA's use of the percent cropped area factors and the Index Reservoir

scenario was reviewed and approved by the FIFRA SAP in 1999 and 1998, respectively (Refs. 30, 31).

In modeling potential surface water concentrations, EPA attempts to model areas of the country that are vulnerable to surface water contamination rather than simply model "typical" concentrations occurring across the nation. Consequently, EPA models exposures occurring in small, highly agricultural watersheds in different growing areas throughout the country, over a 30-year period. The scenarios are designed to capture residue levels in drinking water from reservoirs with small watersheds with a large percentage of land use in agricultural production. EPA's models take into account that pesticide residues in water fluctuate daily, seasonally, and yearly as a result of the timing of pesticide applications, the vulnerability of the water supply to pesticide loading through runoff, spray drift and/or leaching, and changes in the weather. Concentrations are also affected by the method of application, the location and characteristics of the sites where a pesticide is used, the climate, and the type and degree of pest pressure.

EPA uses the output of daily concentration values from tier two modeling as an input to DEEM-FCID, which combines water concentrations with drinking water consumption information in the daily diet to generate a distribution of exposures from consumption of drinking water contaminated with pesticides. These results are then used to calculate a probabilistic assessment of the aggregate human exposure and risk from residues in food and drinking water.

3. *Aggregate Exposure Analyses.* Using probabilistic analyses, EPA combines the national food exposures with the exposures derived for individual

region and crop-specific drinking water scenarios to derive estimates of aggregate exposure. Although food is distributed nationally, and exposures to pesticide residues are therefore not expected to vary substantially throughout the country, drinking water is locally derived and consumed and there can be significant variations in pesticide levels in local watersheds due to geographic, climatic, and other factors. To be protective of all population subgroups, EPA uses modeled estimates from vulnerable watersheds in calculating aggregate exposure.

EPA's standard acute dietary exposure assessment calculates total dietary exposure over a 24-hour period; that is consumption over 24 hours is summed and no account is taken of the fact that eating and drinking occasions may spread out exposures over a day. This total daily exposure generally provides reasonable estimates of the risks from acute dietary exposures, given the nature of most chemical endpoints. Due to the rapid recovery associated with carbofuran toxicity (AChE inhibition), 24-hour exposure periods may or may not be appropriate. To the extent that a day's eating or drinking occasions leading to high total daily exposure might be found close together in time, or to occur from a single eating event, minimal AChE recovery would occur between eating occasions (*i.e.*, exposure events). In that case, the "24-hour sum" approach, which sums eating events over a 24-hour period, would provide reasonable estimates of risk from food and drinking water. Conversely, to the extent that eating occasions leading to high total daily exposures are widely separated in time (within one day) such that substantial AChE recovery occurs between eating occasions, then the estimated risks

under any 24-hour sum approach may be overstated. In that case, a more sophisticated approach—one that accounts for intra-day eating and drinking patterns and the recovery of AChE between exposure events—may be more appropriate. This approach is referred to as the "Eating Occasions Analysis" and it takes into account the fact that the toxicological effect of a first dose may be reduced or tempered prior to a second (or subsequent) dose.

Thus, rather than treating a full day's exposure as a one-time "bolus" dose, as is typically done in the Agency's assessments, the Eating Occasion analysis uses the actual time of eating or drinking occasion, and amounts consumed as reported by individuals to the USDA CSFII. The actual CSFII-recorded time of each eating event is used to "separate out" the exposures due to each eating occasion; in doing so, this "separation" allows the Agency to distinguish between each intake event and account for the fact that at least some partial recovery of AChE inhibition attributable to the first (earlier) exposure occurs before the second exposure event. For chemicals for which the toxic effect is rapidly reversible, the time between two (or more) exposure events permits partial to full recovery from the toxic effect from the first exposure and it is this "partial recovery" that is specifically accounted for by the Eating Occasion Analysis. More specifically, an estimated "persisting dose" from the first exposure event is added to the second exposure event to account for the partial recovery of AChE inhibition that occurs over the time between the first and second exposures. The 'persisting dose' terminology, and this general approach were originally suggested by the FIFRA

SAP in the context of assessing AChE inhibition from cumulative exposures to OP pesticides (Ref. 33).

*C. Selection of Acute Dietary Exposure Level of Concern*

Because probabilistic assessments generally are based on a realistic range of residue values to which the population may be exposed, EPA's starting point for estimating exposure and risk for such aggregate assessments is the 99.9th percentile of the population under evaluation, which represents one person out of every 1000 persons. When using a probabilistic method of estimating acute dietary exposure, EPA typically assumes that, when the 99.9th percentile of acute exposure is equal to or less than the aPAD, the level of concern for acute risk has not been exceeded. By contrast, where the analysis indicates that estimated exposure at the 99.9th percentile exceeds the aPAD, EPA would generally conduct one or more sensitivity analyses to determine the extent to which the estimated exposures at the high-end percentiles may be affected by unusually high food consumption or residue values. To the extent that one or a few values seem to "drive" the exposure estimates at the high end of exposure, EPA would consider whether these values are reasonable and should be used as the primary basis for regulatory decision making (Ref. 77).

**V. Carbofuran Background and Regulatory History**

*A. Tolerance Reassessment and Pesticide Reregistration*

In July 2006, EPA completed a refined acute probabilistic dietary risk assessment for carbofuran as part of the tolerance reassessment program under section 408(q) of the FFDCA and pesticide reregistration under section 4 of FIFRA. The

assessment was conducted using Dietary Exposure Evaluation Model-Food Commodity Intake Database (DEEM-FCID™, Version 200-2.02), which incorporates consumption data from the United States Department of Agriculture's (USDA's) Nationwide Continuing Surveys of Food Intake by Individuals (CSFII), 1994-1996 and 1998, as well as carbofuran monitoring data from USDA's Pesticide Data Program[2] (PDP), estimated percent crop treated information, and processing/cooking factors, where applicable. The assessment was conducted applying an additional 500-fold safety factor that included a 5X children's safety factor, pursuant to section 408(b)(2)(C). That refined assessment showed acute dietary risks from carbofuran residues in food significantly above EPA's level of concern (Ref. 14). Based in part on the results of that assessment, EPA concluded that carbofuran failed to meet the revised safety standard in FFDCA section 408(b) and the standard for FIFRA reregistration.[3]

The tolerance reassessment and FIFRA reregistration process for carbofuran contained numerous opportunities for public participation. These included public comment periods on the preliminary ecological risk assessment (June-August 2005), the

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[2] USDA's Pesticide Data Program monitors for pesticides in certain foods at the distribution points just before release to supermarkets and grocery stores.

[3] Although not relevant to this proceeding, in addition to determining that use of carbofuran resulted in unacceptable dietary risks, EPA concluded that use of carbofuran did not meet the standard for FIFRA registration based on unacceptable occupational and ecological risks.

preliminary human health risk assessment (September-November 2005), the revised combined risk assessment (March-May 2006), and the interim Registration Eligibility Document (RED) (August-November 2006). EPA received over 200 comments (plus a letter campaign supporting carbofuran with 2,896 signatories) to the 2006 RED. FMC submitted extensive comments throughout the process (including, but not limited to, a comment of 62 pages plus 13 attachments totaling over 900 pages on August 23, 2005, a letter with 20 attachments on November 11, 2005, 46 pages of comments on January 26, 2006, 78 pages of comments on February 17, 2006, a 15-page letter with 8 attachments on May 22, 2006, over 200 pages on May 24, 2006, and other submissions. Following issuance of the RED in August 2006, FMC stated that they would be submitting new data to refute EPA's ecological and human health risk concerns, as well as EPA's benefits assessments. Twenty-three submissions with studies and analyses were submitted in 2007, all of which EPA reviewed. FMC submitted 175 pages of comments to the proposed tolerance revocations jointly with the NPC, NCGA, NCC, and NSA on 9/29/09. The Agency has also met numerous times with FMC, growers, and other stakeholders regarding carbofuran.

One particular aspect of the risk assessment process that involved substantial public participation opportunities was EPA's review of the human toxicology studies performed with carbofuran. In making a determination on whether these studies met the standards of the Human Research rule, EPA, as required, sought the advice of the HSRB. The HSRB review process includes the opportunity for the public

both to submit written comments and to make an oral presentation to the HSRB. FMC gave both written and oral comments at the HSRB meeting, which was held May 2-4, 2006. FMC also submitted written comments on the final HSRB report on the meeting.

*B. Draft Notice of Intent to Cancel Carbofuran Registrations*

In January 2008, EPA published a draft Notice of Intent to Cancel (NOIC) all carbofuran registrations, based in part on carbofuran's dietary risks. As mandated by FIFRA, EPA solicited comments from the FIFRA Scientific Advisory Panel (SAP) on its draft NOIC.[4] As part of that process, EPA presented its dietary risk assessment of carbofuran to the FIFRA SAP, and requested comment on key issues in the risk assessment: The Agency's approach to selecting the point of departure and the children's safety factor. FMC and the remaining Petitioners participated in this meeting, making substantial presentations to the SAP. As described in the proposal, the Agency believes that the Panel's responses unambiguously support the Agency's approach with regard to carbofuran's hazard identification and hazard characterization (73 FR 44875 (July 31, 2008)). In addition, EPA believes that, on balance, the application of a 4X children's safety factor is consistent with the SAP's advice. Additional detail on the SAP's advice and EPA's responses can be found at Ref. 83.

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[4] The draft NOIC was based on all of carbofuran's combined risks-dietary, occupational, and ecological. Because some non-food use registrations remain, EPA anticipates issuing the NOIC subsequent to undertaking the activities required to revoke the carbofuran tolerances to cancel these remaining uses.

*C. Proposed Revocation of Carbofuran Tolerances*

Having considered the comments from the SAP, EPA initiated the process to revoke all carbofuran tolerances, publishing a proposed revocation on July 31, 2008 (73 FR 44,864 (July 31, 2008) (FRL-8378-8)). EPA proposed to revoke all of the existing tolerances for residues of carbofuran on the grounds that aggregate exposure from all uses of carbofuran fails to meet the FFDCA section 408 safety standard (Id). Based on the contribution from food alone, EPA calculated dietary exposures to carbofuran exceed EPA's level of concern for all of the more sensitive subpopulations of infants and children. At the 99.9th percentile, aggregate carbofuran dietary exposure from food and drinking water from contaminated ground water was estimated to range from 1100% of the aPAD for adults, to greater than 10,000% of the aPAD for infants, the population subgroup with the highest estimated dietary exposure (Ref. 12). Similarly, aggregate dietary exposures from food and drinking water from surface water, based on contamination from use on corn in Nebraska, ranged from 340% of the aPAD for adults, to 3,900% aPAD for infants. EPA also determined that, based on actual residue levels measured in food in commerce, individual children consuming typical amounts of a single food item received unsafe levels of carbofuran. For example, based on the level of residues detected on in the food supply, a child between 3-5 years, who consumed 1/2 cup of cantaloupe, would receive a dose ranging between 180% and 7,200% of the aPAD. Finally, the proposal discussed a number of sensitivity analyses the Agency had calculated in order to further characterize the potential risks to children. Every one of these sensitivity analyses determined that estimated

exposures significantly exceeded EPA's level of concern for children.

EPA held a 60-day comment period on the proposed revocation rule. In the proposed rule, EPA made clear that if any person had concerns with EPA's proposed revocation, those concerns must be raised during the comment period to be preserved. Specifically, EPA stated:

> In addition to submitting comments in response to this proposal, you may also submit an objection at the time of the final rule. If you anticipate that you may wish to file objections to the final rule, you must raise those issues in your comments on this proposal. EPA will treat as waived, any issue not originally raised in comments on this proposal. Similarly, if you fail to file an objection to the final rule within the time period specified, you will have waived the right to raise any issues resolved in the final rule. After the specified time, issues resolved in the final rule cannot be raised again in any subsequent proceedings on this rule.

(73 FR at 44865).

*D. Petitioners' Comments on the Proposed Rule*

The comment period for the proposed rule closed on September 29, 2008. During the comment period, the Petitioners submitted comments challenging particular aspects of EPA's risk assessment. For example, the Petitioners challenged the basis for EPA's 4X children's safety factor, and the method and assumptions on which EPA relied to estimate drinking water concentrations. In addition, the registrant, FMC Corporation, requested that EPA cancel the use on 22 of the crops on which it was registered, including many

of the foods posing the highest risks to children. FMC also requested that EPA modify its labels to include a number of additional restrictions intended to mitigate the risks identified in EPA's risk assessment. For example, use was prohibited on much of the Eastern US to protect vulnerable sources of groundwater; use restrictions were imposed in other areas of the country, preventing use within set distances to prevent runoff into sources of surface water drinking water supplies.

On November 7, 2008, the Petitioners submitted additional information as a supplement to their September comments. Specifically, they submitted carbofuran use data that the Petitioners used in preparing its surface water assessments. The information consisted of a spreadsheet that contained all of the data provided to the Water Panel by FMC, and a document that explained the materials, methods, and procedures employed by the Panel to utilize this data.

On December 24, 2008, FMC submitted a petition requesting that EPA stay the effective date of the tolerance revocations, and that EPA consider additional information, including further risk mitigation measure that the registrant intended to implement, as well as additional analyses that the Petitioners' experts were developing.

*E. Final Rule Revoking Carbofuran Tolerances*

On May 15, 2009, EPA published its final rule, based on a revised risk assessment that addressed the voluntary cancellations and label restrictions submitted by the close of the September 29 comment period. The only food uses that remained registered after the voluntary cancellations were sunflowers, corn, potatoes, and pumpkins. In response to the changes

made on the labels, EPA revised its risk assessment to account for the reduced number of crops, the altered geographic restrictions, and the additional risk mitigation measures proposed as part of FMC's comments.

Having considered all comments received by the close of the comment period, and based on its revised analyses, EPA concluded that aggregate exposures from all remaining uses of carbofuran were still unsafe for infants and children, and that revocation of the remaining tolerances was warranted. The final rule explained that, although the recent cancellation of several registered uses reduced the dietary risks to children, EPA's analyses still showed that estimated exposures significantly exceed EPA's level of concern for children. For example, EPA determined that the estimated risks could be as high as 9,400% of the aPAD for infants. A detailed description of the risk assessment supporting the final rule follows.

1. *Toxicity.* AChE inhibition in brain and the PNS is the initial adverse biological event which results from exposure to carbofuran, and with sufficient levels of inhibition leads to other effects such as tremors, dizziness, as well as gastrointestinal and cardiovascular effects, including bradycardia (Ref. 15). Thus, AChE inhibition provides the most appropriate effect to use in risk extrapolation for derivation of RfDs and PADs. Protecting against AChE inhibition ensures that the other adverse effects associated with cholinergic toxicity, mentioned above, do not occur.

There are three studies available that compare the effects of carbofuran on eleven-day-old rats (*i.e.*, post-natal day 11 or PND11) rats with those in young adult rats (herein called comparative AChE studies) (Refs. 1,

2, 4, and 66). Two of these studies were submitted by FMC, the registrant, and one was performed by EPA-ORD. An additional study conducted by EPA-ORD involved PND17 rats (Ref. 63). Although it is not possible to directly correlate ages of juvenile rats to humans, PND11 rats are believed to be close in development to newborn humans. PND17 rats are believed to be closer developmentally to human toddlers (Refs. 10, 22, and 23). Other studies in adult rats used in the Agency's analysis included additional data from EPA-ORD (Refs. 54, 62, and 66).

The studies in juvenile rats show a consistent pattern that juvenile rats are more sensitive than adult rats to the effects of carbofuran. These effects include inhibition in AChE in addition to incidence of clinical signs of neurotoxicity such as tremors. This pattern has also been observed for other NMC pesticides, which exhibit the same mechanism of toxicity as carbofuran (Ref. 81). It is not unusual for juvenile rats, or indeed, for infants or young children, to be more sensitive to chemical exposures as metabolic detoxification processes in the young are still developing. Because juvenile rats, called 'pups' herein, are more sensitive than adult rats, data from pups provide the most relevant information for evaluating risk to infants and young children and are thus used to derive the PoD. In addition, typically (and this is the case for carbofuran) young children (ages 0-5 years) tend to be the age groups most exposed to carbofuran because they tend to ingest larger amounts of food and water per their body weight than do teenagers or adults. As such, the focus of EPA's analysis of carbofuran's dietary risk from residues in food and water is on young children (ages 0 to 5 years). Since

these age groups experience the highest levels of dietary risk, protecting these groups against the effects of carbofuran will, in turn, also protect other age groups.

The Agency used a meta-analysis to calculate the $BMD_{10}$ and $BMDL_{10}$ for pups and adults; this analysis includes brain data from studies where either adult or juvenile rats or both were exposed to a single oral dose of carbofuran. The Agency used a dose-time-response exponential model where benchmark dose and half-life to recovery can be estimated together. This model and the statistical approach to deriving the $BMD_{10}$s, $BMDL_{10}$s, and half-life to recovery have been reviewed and supported by the FIFRA SAP (Refs. 34, 35, and 36). The meta-analysis approach offers the advantage over using single studies by combining information across multiple studies and thus provides a robust PoD.

For AChE-inhibiting pesticides, EPA generally evaluates the effects of the pesticide on both brain and RBC AChE. RBC AChE is used as a surrogate for effects on the PNS because data directly measuring effects on the PNS are difficult to obtain.

Using quality brain AChE data from the three studies (two FMC, one EPA-ORD) conducted with PND11 rats, in combination, provides data to describe both low and high doses. By combining the three studies in PND11 animals together in a meta-analysis, the entire dose-response range is covered. The results of the BMD analysis for PND11 pup brain AChE data provide a $BMD_{10}$ of 0.04 mg/kg/day and $BMDL_{10}$ of 0.03 mg/kg/day-this $BMDL_{10}$ of 0.03 mg/kg/day provides the PoD (Ref. 70).

EPA, however, lacked adequate data on carbofuran's effects on RBC AChE. Two studies required from FMC were rejected as flawed. To account for the lack of data in the PNS and/or a surrogate (*i.e.*, RBC AChE inhibition data) in pups at the low end of the response curve, and for the fact that RBC AChE inhibition appears to be a more sensitive point of departure compared to brain AChE inhibition, EPA determined that, consistent with the statutory mandate, some portion of the statutory default 10X children's safety factor needed to be retained. Because there are some carbofuran data that characterize the toxicity in juveniles, EPA concluded that the weight-of-the-evidence supports reducing the statutory factor of 10X to a value lower than 10X. This results in a children's safety factor that is less than 10 but more than 1.

The modified children's safety factor takes into account the greater sensitivity of the RBC AChE. The preferred approach to comparing the relative sensitivity of brain and RBC AChE inhibition would be to compare the $BMD_{10}$ estimates. However, $BMD_{10}$ estimates from the available RBC AChE inhibition data are not reliable due to lack of data at the low end of the dose response curve. As an alternative approach, EPA used the ratio of brain to RBC AChE inhibition at the $BMD_{50}$, since there are quality data at or near the 50% response level such that a reliable estimate can be calculated. EPA estimated the RBC $BMD_{50}$ to brain $BMD_{50}$ potency ratio using EPA's data for RBC (the only reliable RBC data in PND11 animals for carbofuran) and all available data in PND11 animals for brain. There is, however, an assumption associated with using the 50% response level—namely that the

magnitude of difference between RBC and brain AChE inhibition is constant across dose. In other words, EPA is assuming the RBC and brain AChE dose response curves are parallel. There are currently no data to test this assumption for carbofuran.

Comparing RBC BMD50 and brain $BMD_{50}$ AChE inhibition, EPA calculated a $BMD_{50}$ ratio of 4.1X. Accordingly, EPA concluded that a children's safety factor of 4X would be protective of infants and children.

Using the $BMDL_{10}$ of 0.03 mg/kg/day, combined with the default 10X interspecies and intraspecies factors, along with the 4X children's safety factor results in an aPAD = 0.000075 mg/kg/day for infants and children. The aPAD for youths and adults is calculated in the same manner, but EPA does not apply the 4X children's safety factor, resulting in an aPAD of 0.0002 mg/kg/day.

2. *Acute Exposures from Food.* The estimated acute dietary exposure from carbofuran residues in food alone (*i.e.*, assuming no additional carbofuran exposure from drinking water), is below EPA's level of concern for the U.S. Population and all population subgroups. Children 1 to 2 years of age (78% aPAD) were the most highly exposed population subgroup when food only was included. The major driver of the acute dietary exposure risk (food only) for Children 1 to 2 years is milk, at greater than 90% of the exposure.

3. *Acute Exposures from Drinking Water.* EPA's analyses show that those individuals-both adults as well as children—who receive their drinking water from vulnerable sources are exposed to levels that exceed EPA's level of concern—in some cases by

orders of magnitude. This primarily includes those populations consuming drinking water from ground water from shallow wells in acidic aquifers overlaid with sandy soils that have had crops treated with carbofuran. It could also include those populations that obtain their drinking water from reservoirs located in small agricultural watersheds, prone to runoff, and predominated by crops that are treated with carbofuran, although there is more uncertainty associated with these exposure estimates.

a. *Ground Water.* In EPA's revised assessment, ground water concentrations were estimated for all remaining crops on carbofuran labels, and used two new Tier 2 scenarios. Based on a new corn scenario, representative of potentially vulnerable areas in the upper Midwest, EPA estimated 1-in-10-year concentrations for ground water source drinking water of 16 to 1.6 x $10^{-3}$ µg/L, for pH 6.5 and 7, respectively. A potato scenario representing use in the Northwest estimated no measurable concentrations of carbofuran in ground water. Other remaining uses were modeled using a Tier 1 ground water model (Screening Concentration in Groundwater) with estimated peak 90-day concentrations of 48-178 µg/L, depending on application rate. Well setback prohibitions of 50 feet were proposed on the September 2008 label for the flowable and granular formulations in select counties in Kentucky (seven counties), Louisiana (one county), Minnesota (one county), and Tennessee (one county). Analysis of the impact of these setbacks for the use on corn indicated that the setbacks would not reduce concentrations significantly at locations where exposure to carbofuran in ground water is of concern because at acid pHs, carbofuran does not degrade

sufficiently during the travel time from the application site to the well to substantially reduce the concentration.

Exposure estimates for this assessment are drawn primarily from EPA's modeling. To conduct its modeling, EPA examined readily available data with respect to ground water and soil pH to evaluate the spatial variability of pH. Ground water pH values can span a wide range; this is especially true for shallow ground water systems, where local conditions can greatly affect the quality and characteristics of the water (higher or lower pHs compared to average values). The ground water simulations reflect variability in pH by modeling carbofuran leaching in four different pH conditions (pH 5.25, 6.5, 7.0, and 8.7), representing the range in the Wisconsin aquifer system. The upper and lower bound of pH values that EPA chose for this assessment were measured values from the aquifer, and the remaining two values were chosen to reflect common pH values between the measured values. Based on EPA's assessment, the maximum 1-in-10-year peak carbofuran concentrations in vulnerable ground water for a single application on corn in Wisconsin, at a rate of 1 pound per acre were estimated to range from a low of less than 1 ppb based on a pH of 7 or higher, to a high of 16 ppb, based on a pH of 6.5.

The results of EPA's revised corn modeling, based on a scenario in Wisconsin, are consistent with the results of the PGW study developed by FMC in Maryland in the early 1980s. Using higher use rates than currently permitted, the peak concentration measured in the PGW study was 65 ppb; when scaled to current use rates, the estimated peak concentration

was 11 ppb. EPA's modeling is also consistent with a number of other targeted ground water studies conducted in the 1980s showing that high concentrations of carbofuran can occur in vulnerable areas; the results of these studies as well as the PGW study are summarized in References 13 and 67.

While there have been additional ground water monitoring studies that included carbofuran as an analyte since that time, there has been no additional monitoring targeted to carbofuran use in areas where aquifers are vulnerable. However, data compiled in 2002 by EPA's Office of Water show that carbofuran was detected in treated drinking water at a few locations. Based on samples collected from 12,531 ground water supplies in 16 states, carbofuran was found at one public ground water system at a concentration of greater than 7 ppb and in two ground water systems at concentrations greater than 4 ppb (measurements below this limit were not reported). An infant receiving these concentrations would receive doses equivalent to 220% of the aPAD or 130% aPAD, respectively, based on a single 8 ounce serving of water. As this monitoring was not targeted to carbofuran, the likelihood is low that these samples capture peak concentrations. Given the lack of targeted monitoring, EPA has primarily relied on modeling to develop estimates of carbofuran residues in ground water sources of drinking water.

EPA compiled a distribution of estimated carbofuran concentrations in water based on these estimates, which was used to generate probabilistic assessments of the potential exposures from drinking water derived from vulnerable ground water sources. Based on these assessments, estimated exposures

ranged between 770% aPAD for adults to 9400% aPAD for infants.

b. *Surface Water.* For the final rule, EPA conducted additional refined modeling based on the September 2008 label submitted by FMC. The modeling addressed all of the domestic uses that remain registered, and included certain refinements to better understand the impacts of varying pH. EPA also conducted modeling to assess the impact of the proposed spray drift buffer requirements and other spray drift measures included on the September label.

EPA estimated carbofuran concentrations resulting from the use on pumpkins by adjusting the estimated drinking water concentrations (EDWC) from a previous run simulating melons in Missouri; adjustments accounted for differences in application rate and row spacing. Two EDWCs were calculated for pumpkins: One based on a 36-inch row spacing, representing pumpkins for consumption (77.6 ppb); and a second based on a 60-inch row spacing, representing decorative pumpkins (46.6 ppb).

EPA had previously evaluated the corn rootworm rescue treatment at seven representative sites, representing use in states with extensive carbofuran usage at locations more vulnerable than most in each state in areas corn is grown. Using measured rainfall values, and assuming typical rather than maximum use rates, peak concentrations for the corn rescue treatments simulated for Illinois, Iowa, Indiana, Kansas, Minnesota, Nebraska, and Texas ranged from 16.6-36.7 ppb (Ref. 47). Under the revised assessment to account for the September 2008 use restrictions, concentrations for corn, calculated including the proposed spray drift buffers in Kansas and Texas,

decreased 5.1% and 4.7%, respectively, from simulations with no buffer from the previous assessment (Ref. 47). In Kansas, the 1-in-10-year peak EDWCs decreased from 33.5 to 31.8 ppb when a 300-foot buffer was added, and in Texas, from 29.9 to 28.5 ppb with the addition of a 66-foot buffer.

For the sunflower use, 12 simulations were performed for sunflowers, 9 in Kansas, and 3 in North Dakota. The North Dakota scenario was used to represent locations where sunflowers are grown that are vulnerable to pesticide movement to surface water while the Kansas scenario represents places that are not particularly vulnerable, based on the limited rainfall and generally well-drained soils (hydrologic group B soils) that are found in that area. Estimated 1-in-10-year concentrations ranged from 11.6 to 32.7 µg/L. When simulating three applications, one at plant and two foliar with a 14-day interval between the two foliar applications and a 66-foot buffer, the 1-in-10-year peak EDWC for North Dakota was 22.4 µg/L. In contrast, the same three applications in Kansas with a 14-day interval between the foliar applications and a 300-foot buffer produced a 1-in-10-year peak EDWC of 20.5 µg/L. The 1-in-10-year peak EDWCs, assuming that carbofuran is applied only at plant, were 14.0 and 16.0 µg/L in Kansas and North Dakota respectively. EPA also evaluated the impact of pH on carbofuran concentrations for sunflowers, resulting in a 10% decrease in 1-in-10-year peak concentrations assuming high pH in the reservoir. Spray drift buffers of 66 and 300 feet decreased concentrations 4.7 and 5.1% for corn and 10.0% and 16.0% for sunflowers, respectively, in comparison to previous labels that had no spray drift

buffer requirements. Additional details on these assessments can be found at Reference 84.

These predicted carbofuran water concentrations are similar or lower than the peak concentrations reported in the United States Geological Survey-National Ambient Water Quality Survey (USGS-NAWQA) monitoring data. In addition, these data, which represent concentrations in surface water prior to any treatment by a public drinking water system, are consistent with the results of the 2002 data on finished water compiled by EPA's Office of Water. Based on samples collected from 1,394 surface water source drinking water supplies in 16 states, carbofuran was found at no public drinking water supply systems at concentrations exceeding maximum contaminant level (MCL) of 40 ppb. However, carbofuran was found at one surface water public water system in finished (*i.e.*, post-treatment) water at concentrations greater than 4 ppb (measurements below this limit were not reported). Sampling is costly and is conducted typically four times a year or less at any single drinking water facility. The overall likelihood of collecting samples that capture peak exposure events is, therefore, low. For chemicals with acute risks of concern, such as carbofuran, higher concentrations and resulting risk is primarily associated with these peak events, which are not likely to be captured in monitoring unless the sampling rate is very high.

There are few surface water field-scale studies targeted to carbofuran use that could be compared with modeling results. Most of these studies were conducted in fields that contain tile drains, which is a common practice throughout midwestern states to increase drainage in agricultural fields (Ref. 13).

Drains are common in the upper Mississippi river basin (Illinois, Iowa, and the southern part of Minnesota), and the northern part of the Ohio River Basin (Indiana, Ohio, and Michigan) (Ref. 58). Although it is not possible to directly correlate the concentrations found in most of the studies with drinking water concentrations, these studies confirm that carbofuran use under such circumstances can contaminate surface water, as tile drains have been identified as a conduit to transport water and contaminants from the field to surface waters.

EPA conducted dietary exposure analyses based on the modeling scenarios for the proposed September 2008 label. Exposures from all modeled scenarios substantially exceeded EPA's level of concern (Ref. 12). For example, a Kansas sunflower scenario, assuming two foliar applications at a typical 1 lb active ingredient (a.i.) per acre use rate, applied at 14-day intervals, estimated a 1-in-10-year peak carbofuran water concentration of 11.6 ppb. Exposures at the 99.9th percentile based on this modeled distribution ranged from 160% of the aPAD for youths 13 to 19 years, to greater than 2,000% of the aPAD for infants. This scenario is intended to be representative of sites that are less vulnerable than most on which sunflowers could be grown. By contrast, exposure estimates from a comparable North Dakota sunflower scenario, intended to represent more vulnerable sites, estimated a 1-in-10-year peak concentration of 22.4 ppb. These concentrations would result in estimated exposures ranging between 450% aPAD for youths 13 to 19 years, to 5,500% aPAD for infants. Similarly, exposures based on a Washington surface water potato scenario, and using a 3 lb a.i. acre rate,

ranged from 230% of the aPAD for children 6 to 12 years to 890% of the aPAD for infants, with a 1-in-10-year peak carbofuran concentration of 7.2 ppb. Although other crop scenarios resulted in higher exposures, estimates for these two crops are presented here, as they are major crops on which a large percentage of carbofuran use occurs. For example, one of EPA's refined exposure analyses is based on a Nebraska corn rootworm "rescue treatment" scenario, and assumes a single aerial application at a typical rate of 1 lb a.i. per acre. The full distribution of daily concentrations over a 30-year period was used in the probabilistic dietary risk assessment. The 1-in-10-year peak concentration of the distribution of values for the Nebraska corn rescue treatment was 22.3 ppb. Estimated dietary exposures based on these concentrations ratned from 340% of the aPAD for adults to 3900% of the aPAD for infants. More details on these assessments, as well as the assessments EPA conducted for other crop scenarios, can be found in References 12, 47, and 67.

4. *Aggregate (food and water) Exposures.* EPA conducted a number of probabilistic analyses to combine the national food exposures with the exposures from the individual region and crop-specific drinking water scenarios. Although food is distributed nationally, and residue values are therefore not expected to vary substantially throughout the country, drinking water is locally derived and consumed and concentrations of pesticides in source water fluctuate over time and location for a variety of reasons. Consequently, EPA conducted several estimates of aggregate dietary risks by combining exposures from food and drinking water. These estimates showed that,

because drinking water exposures from any of the crops on the label exceed safe levels, aggregate exposures from food and water are unsafe. Although EPA's assessments showed that, based on the Idaho potato scenarios, exposures from ground water from use on potatoes would be safe, surface water exposures from carbofuran use on potatoes far exceed the safety standard. More details on the individual aggregate assessments presented below, as well as the assessments EPA conducted for other regional and crop scenarios, can be found in References 12 and 13.

The results of aggregate exposures from food and from drinking water derived from ground water in extremely vulnerable areas (*i.e.*, from shallow wells associated with sandy soils and acidic aquifers, such as are found in Wisconsin), ranged from 780% of the aPAD for adults, to 9,400% of the aPAD for infants.

The results of aggregate exposure from food and water derived from one of the least conservative surface water scenarios—Kansas sunflower, with two foliar applications—ranged from 190% of the aPAD for adults to 2,100% aPAD for infants. These estimates reflect the risks only for those people in watersheds with characteristics similar to that used in the scenario, and assuming that water treatment does not remove carbofuran. The estimated water concentrations are comparable to the maximum peak concentrations reported in monitoring studies that were not designed to detect peak, daily concentrations of carbofuran in vulnerable locations.

More details on this assessment, as well as the assessments EPA conducted for other crop scenarios, can be found in References 12, 47, and 67. For example, in the proposed rule, EPA presented the

results from aggregate exposures resulting from a Nebraska surface water scenario based on a Nebraska corn rootworm "rescue treatment." Estimated exposures from that scenario ranged from 330% of the aPAD for youths 13 to 19 years to 3,900% of the aPAD for infants.

As noted previously, EPA's food and water exposure assessments typically sum exposures over a 24-hour period, and EPA used this 24-hour total in developing its acute dietary risk assessment for carbofuran. Because of the rapid nature of carbofuran toxicity and recovery, EPA conducted an analysis using information about dietary exposure, timing of exposure within a day, and half-life of AChE inhibition from rats to estimate risk to carbofuran at durations less than 24 hours. Specifically, EPA has evaluated individual eating and drinking occasions and used the AChE half-life to recovery information (herein called half-life information) to estimate the residual effects from carbofuran from previous exposures within the day. The carbofuran analyses are described in the 2009 aggregate (dietary) memo (Ref. 55).

Using the two FMC time course studies in rat pups, EPA calculated half-lives for recovery of 186 and 426 minutes (Refs. 24 and 25). The two values provide an indication that half-lives to recovery can vary among juvenile rats. By extension, children are expected to vary in their ability to recover from AChE inhibition where longer recoveries would be associated with a potentially higher "persisting dose" (as described below).

This analysis had little impact on the exposures from food alone. However, accounting for drinking water consumption throughout the day and using the

half-life to recovery information, risk is reduced by approximately 2-3X. Consequently, risk estimates for which food and drinking water are jointly considered and incorporated (*i.e.*, Food + Drinking Water) are also reduced considerably—by a factor of two or more in some cases—compared to baseline. But even though the risk estimates from aggregate exposure are reduced, they nonetheless still substantially exceed EPA's level of concern for infants and children. Using drinking water derived from the surface water from the Idaho potato surface water scenario, which estimated one of the lowest exposure distributions, aggregate exposures at the 99.9th percentile ranged from 328% of the aPAD under the scenario for which infants rapidly metabolize carbofuran (*e.g.*, 186 minute half-life), to a high of 473% of the aPAD under the scenario for which infants metabolize carbofuran more slowly, (*e.g.*, scenarios in which a 426 minute half life is assumed).

Moreover, even accounting for the estimated decreased risk from accounting for carbofuran's rapid reversibility, the Agency remains concerned about the risks from single eating or drinking events, as illustrated in the following example, based on an actual food consumption diary from the CSFII survey. A 4-month old male non-nursing infant weighing 10 kg is reported to have consumed a total of 1,070 milliters (ml) of indirect water over eight different occasions during the day. The first eating occasion occurred at 6:30 a.m., when this 4 month old consumed 8 fluid ounces of formula prepared from powder. The FCID food recipes indicate that this particular food item consists of approximately 87.7% water, and therefore, 8 ounces of formula contains approximately 214 ml (or

grams) of indirect water; with the powder (various nutrients, dairy, soy, oils, etc.) accounting for the remaining 12.3%. This infant also reportedly consumed a full 8-ounce bottle of formula at 12 p.m., 4 p.m., and 8 p.m. that day. The food diary also indicates that the infant consumed about 1 tablespoon of water (14.8 ml) added to prepare rice cereal at 10 a.m., about 2 ounces of water (59.3 ml) added to pear juice at 11 a.m., another 1/2 tsp of water (2.5 ml) to prepare more rice cereal at 8:30 p.m.; and finally, he consumed another 4 ounces of formula (107 ml) at 9:30 p.m.

The infant's total daily water intake (1,070 ml, or approximately 107 ml/kg/day) is not overly conservative, and represents substantially less than the 90th percentile value from CSFII on a ml water/kg bodyweight (ml/kg/bw) basis. As noted, carbofuran has been detected in finished water at concentrations of 4 ppb. For this 10 kg body weight infant, an 8-ounce bottle of formula prepared from water containing carbofuran at 4 ppb leads to drinking water exposures of 0.0856 micrograms of active ingredient/kilogram of bodyweight (µg ai/kg bw), or 114% of the aPAD. Based on the total daily water intake of 1,070 ml/day (no reversibility), total daily exposures from water at 4 ppb concentration would amount to 0.4158 µg ai/kg bw, or 555% of the aPAD; this is the amount that would be used for this person-day in the Total Daily Approach.

Peak inhibition occurs following each occasion on which the infant consumed 8 fluid ounces of formula (6 a.m., 12 p.m., 4 p.m. and 8 p.m.); however, the maximum persisting dose occurs following the 9:30 p.m. eating occasion, based on a 186-minute half-life parameter. This produces a maximum persisting dose of 0.1457 µg ai/kg bw, or about 30% of the total daily

exposure of 0.4158 µg ai/kg bw derived above, or expressed as a fraction of the level of concern, the maximum persisting dose amounts to about 194% of the aPAD (or 30% of 554%). Note that with drinking water concentration at 4 ppb, an infant consuming one 8 oz bottle of formula-prepared from powder and tap water containing carbofuran at 4 ppb will obtain exposures of approximately 114% of aPAD. Since many infants consume the equivalent of this amount on a single eating occasion, accounting for reversibility over multiple occasions is not essential to ascertain that infants quite likely have obtained drinking water exposures to carbofuran exceeding the level of concern based on drinking water concentrations found in public drinking water supplies.

In this regard, it is important to note EPA's Eating Occasion Analyses underestimate exposures to the extent that they do not take into account carry-over effects from previous days, and because drinking water pesticide concentrations are randomly picked from the entire 30-year distribution. As discussed previously, DEEM-FCID [FN(TM)] is a single day dietary exposure model, and the DEEM-based Eating Occasion Analysis accounts for reversibility within each simulated person-day. All of the empirical data regarding time and amounts consumed (and corresponding exposures based on the corresponding residues) from the CSFII survey are used, along with the half-life to assess an equivalent persisting dose that produced the peak inhibition expected over the course of that day. This is a reasonable assumption for food alone; since the time between exposure events across 2 days is relatively high (compared to the half-life)—most children (•9 months) tend to sleep through the

night—and the time between dinner and breakfast the following morning is long enough it is reasonable to "ignore" persisting effects from the previous day. A single day exposure model will underestimate the persisting effects from drinking water exposures (formula) among infants, and newborns in particular (<3 months), since newborns tend to wake up every 2 to 4 hours to feed. Any carry over effects may be important, especially if exposures from the previous day are relatively high, since the time between the last feeding (formula) of the day and the first feeding of the subsequent day is short. A single day model also does not account for the effect of seasonal variations in drinking water concentrations, which will make this effect more pronounced during the high use season (*i.e.*, the time of year when drinking water concentrations are high). Based on these analyses, the Agency concludes that the current exposure assessment methods used in the carbofuran dietary assessment provide realistic and high confidence estimates of risk to carbofuran exposure through food and water.

*F. Response to FMC Comments on the Final Rule*

FMC's comments raised a range of issues. Those issues are not summarized here because FMC basically refilled many of its comments as objections without modifying them in response to EPA's decision in the final rule. In addition, FMA submitted a an alternate risk analysis purporting to show that aggregate carbofuran exposures to children would be safe. However, FMC failed to provide the data and details of that assessment to the Agency. They also failed to provide several critical components that served to support key inputs into that assessment; and for several of these, EPA was unable to replicate the

claimed results based on the information contained in the comments. In the absence of such critical components, the Agency was unable to accept the validity or utility of the analyses, let alone rely on the results.

Nonetheless, based on the summary descriptions provided in the registrant's comments, EPA concluded that the risk analyses contained a critical flaw. The commenters' determination of safety rests on the presumption that under real world conditions, events will always occur exactly as hypothesized by the multiple assumptions in their assessment. For example, the comments assumed, despite all available evidence to the contrary, that children would not be appreciably more sensitive to carbofuran's effects than adults. They assumed that carbofuran's effects will be highly reversible, and that children will be uniformly sensitive, such that the effects will be adequately accounted for by the assumption of a 150-minute half-life, despite the fact that children are not uniformly sensitive. They further assumed that there would be no carry over effect from the preceding day's exposures for infants. They assumed that the cancellation of use on alfalfa would reduce carbofuran residues in milk by over 70%, even though many cows' diet consists primarily of corn. They assumed that residues would decrease between 19% and 23% as a result of the buffer requirements on the September 2008 label, even though the label does not require the use of all of the recommended "best management practices" (*e.g.*, no requirements regarding swath displacement), and applicators do not universally use such practices in the absence of any requirement. They assumed that average ground

water pH adequately characterizes the temporal and spatial heterogeneity common in most areas, despite the available evidence to the contrary. Finally, they assumed that the percent of the crop treated in any watershed would never exceed 5%, despite varying pest pressures, consultant recommendations, and individual grower decisions. Leaving aside that EPA believes most, if not all of these assumptions are not supported by the available evidence described throughout the final rule, the probability of all these assumptions always simultaneously holding true under real world conditions is unreasonably low, and certainly does not approach the degree of certainty necessary for EPA to conclude that children's exposures will be safe.

Determining whether residues will be safe for U.S. children is not a theoretical paper exercise; it cannot suffice to hypothesize a unique set of circumstances that make residues "fit in the box." There must be a reasonable certainty that under the variability that exists under real world conditions, exposures will be "safe." EPA's assessments incorporate a certain degree of conservatism precisely to account for the fact that assumptions must be made that may not prove accurate. This consideration is highly relevant for carbofuran, because as refined as EPA's assessments are, areas of uncertainty remain with regard to carbofuran's risk potential. For example, a recent epidemiological study reported that 45% of maternal and cord blood samples in a cohort of New York City residents of Northern Manhattan and the South Bronx between 2000 and 2004, contained low, but measurable residues of carbofuran (Ref. 88). The Agency is currently unable to account for the source of such sustained exposures at this frequency.

A further consideration is that the risks of concern are acute risks to children. For acute risks, the higher values in a probabilistic risk assessment are often driven by relatively high values in a few exposures rather than relatively lower values in a greater number of exposures. This is due to the fact that an acute assessment looks at a narrow window of exposure where there are unlikely to be a great variety of consumption sources. Thus, to the extent that there is a high exposure it will be more likely due to a high residue value in a single consumption event. Additionally worrisome in this regard is that carbofuran is a highly potent (*i.e.*, has a very steep dose-response curve), acute toxicant, and therefore any aPAD exceedances are more likely to have greater significance in terms of the potential likelihood of actual harm. For all of these reasons, EPA determined that the existing carbofuran tolerances did not meet the FFDCA safety standard, and should therefore be revoked.

## VI. Response to Objections and Requests for Hearing

### *A. Overview*

Petitioners raised several objections that correspond to four basic categories of issues. The first category of objections and hearing requests relates to challenges to EPA's selection of the appropriate children's safety factor. In this category of issues, they raise primarily two claims: (1) That EPA's scientific basis for retaining a 4X safety factor is flawed, and (2) the statistical calculations supporting the 4X safety factor are flawed, and based on faulty assumptions. The second category of issues relate to the manner in which EPA conducted its assessment of the exposure

from carbofuran through drinking water sources. In this regard, all of their objections fall within three basic categories of issues: (1) EPA should have accounted for a more realistic percent of the crop treated (PCT) in its surface water modeling; (2) EPA's ground water concentration estimates are not based on the best available data, but on obsolete data and overly conservative assumptions; and (3) FMC's new label restrictions and revised terms of registration will ensure that drinking water concentrations will not exceed 1.1 ppb. The third category of issues relates to the manner in which EPA conducted its dietary risk assessment. Under this category, the objections and hearing requests raise four primary issues: (1) Petitioners challenge the way in which EPA's risk assessments accounted for individuals to recover from the effects of carbofuran between exposures; (2) EPA should have relied on the carbofuran human study and therefore use of the default 10X interspecies factor is inconsistent with the "best available data; (3) the import tolerances by themselves are safe and EPA should have retained them even if EPA believed tolerances associated with the domestic uses were unsafe; and (4) Petitioners claim that the combined food and water exposures are safe, based on FMC's drinking water estimates of a 1.1 ppb maximum concentration, which are guaranteed by new label restrictions submitted as part of objections. Finally, Petitioners raise one legal objection unaccompanied by a hearing request. They argue that EPA lacks authority to limit issues and supporting information that can be raised in objections and hearing to those raised in earlier comments.

EPA denies each of the Petitioners' objections as well as their hearing requests. In the first instance, EPA denies Petitioners' objections and their hearing requests because the objections are inextricably intertwined with proposed changes to carbofuran's FIFRA registration that were not submitted until after publication of the final tolerance revocation rule. Objections to EPA's decision based on FIFRA registration amendments proposed after EPA's decision are irrelevant, and thus immaterial, to a challenge to EPA's decision (See Unit VI.C.). Secondly, an individual analysis of Petitioners' objections and hearing requests leads to the same conclusion for the reasons summarized below.

The Petitioners' hearing requests fail to meet the statutory and regulatory requirements for holding a hearing. In most cases, EPA has denied the request on the grounds that the objection is irrelevant, and therefore immaterial, with regard to EPA's final tolerance revocation regulation. In particular, many claims are immaterial because they largely restate the claims in their combined comments on EPA's proposed rule without challenging the substance or even responding to EPA's explanations for the reasons that EPA declined to adopt the approaches or otherwise make the revisions suggested by the Petitioners in their comments. These claims are irrelevant to the determinations reached in the final rule. In several instances, EPA concluded that Petitioners evidentiary proffer was inadequate, because the data and information submitted, even if accurate, would be insufficient to justify the factual determination urged, or to resolve one or more of the issues in their favor. Further, in many cases, the evidence submitted

constituted mere allegations and general denials and contentions, which EPA regulations expressly provide to be insufficient to justify a hearing. In addition, many of Petitioners' claims do not present genuine and substantial issues of fact and/or are immaterial to the relief requested.

On the merits, the majority of Petitioners' objections are denied for substantially the same reasons given in EPA's final rule and response to comments. As noted, many of Petitioners' objections are simply their recycled comments which do not address the conclusions reached by EPA in the final rule. To the extent a response is even needed to such a stale claim, it is provided in the final rule and the response to comments.

The remainder of this Unit is organized in the following manner. Unit VI.B describes in greater detail the requirements pertaining to when it is appropriate to grant a hearing request. In Unit VI.C, EPA generally denies all of Petitioners' objections and hearing requests. Unit VI.D provides EPA's response to the Petitioners legal objection that EPA lacks the legal authority to limit the issues and supporting information that can be raised in an objection and hearing to those raised in comments on the proposed rule. Units VI. G and I provide Petitioners' claims regarding EPA's risk assessment. EPA's conclusions on the hearing requests and objections are summarized in Unit VI.K.

EPA has adopted a 4-part format in Units VI.E through I. for explaining its ruling on each of the subissues EPA identified in the objections. First, the Petitioners' claim and any arguments or evidence tendered to support that claim are described. Second,

background information on the claim is provided including whether and how the claim was presented in Petitioners' comments and, if it was presented, EPA's reasons for denying the claim in its final rule and response to comments. Third, EPA explains its reasons for denying a hearing on that claim. Finally, EPA explains its reasons for denying the claim on the merits.

*B. The Standard for Granting an Evidentiary Hearing*

EPA has established regulations governing objections to tolerance rulemakings and tolerance petition denials and requests for hearings on those objections. (40 CFR Part 178; 55 FR 50291 (December 5, 1990)). Those regulations prescribe both the form and content of hearing requests and the standard under which EPA is to evaluate requests for an evidentiary hearing.

As to the form and content of a hearing request, the regulations specify that a hearing request must include: (1) A statement of the factual issues on which a hearing is requested and the requestor's contentions on those issues; (2) a copy of any report, article, or other written document "upon which the objector relies to justify an evidentiary hearing;" and (3) a summary of any other evidence relied upon to justify a hearing. (40 CFR 178.27).

The standard for granting a hearing request is set forth in section 178.32. That section provides that a hearing will be granted if EPA determines that the "material submitted" shows all of the following:

> (1) There is a genuine and substantial issue of fact for resolution at a hearing. An evidentiary

hearing will not be granted on issues of policy or law.

(2) There is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary. An evidentiary hearing will not be granted on the basis of mere allegations, denials, or general descriptions of positions and contentions, nor if the Administrator concludes that the data and information submitted, even if accurate, would be insufficient to justify the factual determination urged.

(3) Resolution of the factual issue(s) in the manner sought by the person requesting the hearing would be adequate to justify the action requested. An evidentiary hearing will not be granted on factual issues that are not determinative with respect to the action requested. For example, a hearing will not be granted if the Administrator concludes that the action would be the same even if the factual issue were resolved in the manner sought.

(40 CFR 178.32(b)).

This provision essentially imposes four requirements upon a hearing requestor. First, the requestor must show it is raising a question of fact, not one of law or policy. Hearings are for resolving factual issues, not for debating law or policy questions. Second, the requestor must demonstrate that there is a genuine dispute as to the issue of fact. If the facts are undisputed or the record is clear that no genuine dispute exists, there is no need for a hearing. Third,

the requestor must show that the disputed factual question is material—*i.e.*, that it is outcome determinative with regard to the relief requested in the objections. Finally, the requestor must make a sufficient evidentiary proffer to demonstrate that there is a reasonable possibility that the issue could be resolved in favor of the requestor. Hearings are for the purpose of providing objectors with an opportunity to present evidence supporting their objections as the regulation states, hearings will not be granted on the basis of "mere allegations, denials, or general descriptions of positions or contentions." (40 CFR 178.32(b)(2)).

EPA's hearing request requirements are based heavily on FDA regulations establishing similar requirements for hearing requests filed under other provisions of the FFDCA (53 FR 41126, 41129 (October 19, 1988)). FDA pioneered the use of summary judgment-type procedures to limit hearings to disputed material factual issues and thereby conserve agency resources. FDA's use of such procedures was upheld by the Supreme Court in 1972, (Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609 (1973)), and, in 1975, FDA promulgated generic regulations establishing the standard for evaluating hearing requests (40 FR 22950 (May 27, 1975)). It is these regulations upon which EPA relied in promulgating its hearing regulations in 1990.

Unlike EPA, FDA has had numerous occasions to apply its regulations on hearing requests. FDA's summary of the thrust of its regulations, which has been repeatedly published in the **Federal Register** in orders ruling on hearing requests over the last 24

years, is instructive on the proper interpretation of the regulatory requirements. That summary states:

> A party seeking a hearing is required to meet a threshold burden of tendering evidence suggesting the need for a hearing.' [] An allegation that a hearing is necessary to sharpen the issues' or fully develop the facts' does not meet this test. If a hearing request fails to identify any evidence that would be the subject of a hearing, there is no point in holding one.
>
> A hearing request must not only contain evidence, but that evidence should raise a material issue of fact concerning which a meaningful hearing might be held. [] FDA need not grant a hearing in each case where an objection submits additional information or posits a novel interpretation of existing information. [] Stated another way, a hearing is justified only if the objections are made in good faith and if they "draw in question in a material way the underpinnings of the regulation at issue." Finally, courts have uniformly recognized that a hearing need not be held to resolve questions of law or policy

(49 FR 6672, 6673 (February 22, 1984); 72 FR 39557, 39558 (July 19, 2007) (citations omitted)).

EPA has been guided by FDA's application of its regulations in this proceeding. Congress confirmed EPA's authority to use summary judgment-type procedures with hearing requests when it amended FFDCA section 408 in 1996. Although the statute had been silent on this issue previously, the FQPA added language specifying that when a hearing is requested, EPA "shall * * * hold a public evidentiary hearing if

and to the extent the Administrator determines that such a public hearing is necessary to receive factual evidence relevant to material issues of fact raised by the objections" (21 U.S.C. 346a(g)(2)(B)). This language grants EPA broad discretion to determine whether a hearing is "necessary to receive factual evidence" to objections (H.R. Rep. No. 104-669, at 49 (1996)).

*C. General Denial of Objections and Hearing Requests*

Petitioners' objections and hearing requests are denied in their entirety as irrelevant, and therefore immaterial, to EPA's determination in the May 15, 2009 final rule that the carbofuran tolerances were unsafe and could not be sustained under FFDCA section 408. In that final rule, EPA assessed the risks from carbofuran based on existing uses of carbofuran, as modified by all use restrictions proposed by FMC. EPA concluded that the carbofuran tolerances substantially exceeded the FFDCA safety standard, particularly as to infants and children.

Petitioners' objections and hearing requests as to that final rule disclose on their face their irrelevance to the conclusions reached in the May 15, 2009 final rule. As Petitioners summarize their objections on the first page of their submission:

> Petitioners disagree that the carbofuran tolerances are unsafe and argue that the available scientific data show that there is a reasonable certainty of no harm to human health from the continued use of carbofuran for certain specific uses and related tolerances under the terms for reregistration proposed by Petitioners.

(Objections at 1) (footnote omitted) (emphasis added). As Petitioners' footnote to this sentence reveals, however, the proposed terms for FIFRA reregistration referenced by Petitioners include significant terms submitted to EPA on June 29, 2009, 44 days after publication of the final rule revoking carbofuran's FFDCA tolerances. In fact, the body of Petitioners' objections show that FMC's June 29, 2009 proposed FIFRA registration amendments are inextricably intertwined with the claims made in the objections. Thus, Petitioners are actually not objecting to the conclusions in EPA's final rule; rather, they are suggesting that EPA might reach a different result in a different factual scenario.

Objections, however, must be directed "with particularity [at] the provisions of the regulation or order deemed objectionable." 21 U.S.C. 346a(g)(2). The key here is that a party must file particularized objections to—that is, identify some type of error in—a specific regulatory decision. In no sense, however, can it be claimed that EPA erred, or that there is something objectionable, in its May 15, 2009 file rule because EPA did not consider a proposed revision to the terms of the carbofuran registration that had not yet been made. EPA need not shoot at a moving target, much less a target that is not in existence. Therefore, Petitioners' objections are irrelevant, and thus immaterial, to the May 15, 2009 final rule; they are based on hypothetical terms of carbofuran use not before the Agency as it made its determination in that final rule.

Moreover, it is not as if Petitioners' proposed terms for carbofuran use are simple, straightforward use deletions that could be immediately effectuated. While such a proposal is still irrelevant as a challenge to a

prior EPA determination, such a proposal might lead EPA to expeditiously modify its action. Rather, Petitioners have proposed an unprecedented scheme involving FMC playing a role as a middleman between EPA and growers to ensure that carbofuran use in no one area exceeds a certain percentage of the cropped area. FMC has properly filed proposed amendments to its FIFRA registration, which would incorporate these new restrictions on carbofuran use and EPA will review these proposals consistent with the substantive and procedural requirements of FIFRA. At such time as these new terms of registration are determined by EPA to meet the standard for registration, and not before, would it be appropriate for EPA to consider whether the tolerance revoked by the May 15, 2009 rule should be re-established.

Finally, Petitioners argue that it can raise its proposed terms of carbofuran use because EPA cannot limit them from putting forward new issues in a hearing. As explained below, EPA believes Petitioners have misconstrued the law on this point. However, even assuming for the sake of argument that Petitioners are correct that new issues can be raised at a hearing on objections, Petitioners admit that any newly raised issues must meet the standard of relevance. As explained above, however, objections based on terms or FIFRA registration proposed after EPA's final rule are irrelevant to the correctness of EPA's determination in that final rule.

EPA has nonetheless evaluated each of Petitioners' objections and hearing requests and determined that there are alternate grounds for denying them. (See Units VI.E through I). EPA has undertaken this analysis for all of the objections despite the fact that it

is not at all clear that those of Petitioners' claims which appear to be unrelated to FMC's recently proposed registration amendments would either individually or collectively change EPA's safety determination for the carbofuran tolerances given the relatively high level of risk estimated for the carbofuran tolerances in the final revocation rule. Petitioners have certainly not provided any road map as to how a safety finding could be made absent FMC's recently-proposed registration amendments. The failure to make such a showing is further justification for EPA's denial of Petitioners' objections and hearing requests.

*D. Response to Petitioners' Objection That EPA Lacks the Authority To Limit the Issues That May Be Raised in Objections and Hearing Requests*

*1. Response to Legal Issue.* Petitioners claim that EPA lacks the authority to restrict the issues that may be raised as part of their objections. Specifically, they challenge EPA's interpretation that the failure to raise issues or provide information during the comment period on the proposed rule bars consideration of such issues or evidence as part of submitted objections or hearings. Petitioners make two arguments in support of this contention: (1) That neither FFDCA section 408(g) on its face nor EPA's regulations implementing FFDCA section 408(g) limit the issues that can be raised in objections, or in any hearing; and (2) that even though the rulemaking phase is governed by 553 of the Administrative Procedure Act (APA), the hearing must be held in accordance with APA sections 556 and 557, which requires that the "exclusive record for decision must consist of testimony and exhibits received at the hearing, as well as other papers filed in the hearing proceeding" (Obj at 64). On this basis, the

Petitioners conclude that all of the cases cited in the Final Rule requiring parties to raise all issues and information on which they intend to rely in subsequent proceedings are inapplicable.

These arguments are premised on several fundamental misconstructions of the FFDCA section 408 and the APA. None of the cases they cite address the specific question of whether and how the requirements of section 553 of the APA apply to FFDCA section 408. And for many of these cases, Petitioners misquote the cases, misinterpret the holdings, or misconstrue language taken out of context.

Petitioners' first argument, that neither section 408(g) nor EPA's regulations limit the issues that can be raised in objections or in any hearing, is incorrect and misses the point. As discussed at length in the Final Rule, the provisions of 408(g) are not to be viewed in isolation, but as part of a coherent statutory structure inextricably linked to the FFDCA's informal rulemaking procedures and section 553 of the APA. Petitioners concede that FFDCA section 408 establishes an informal rulemaking process (Obj at 62-63). As an informal rulemaking, the process is governed by section 553 of the APA and the case law interpreting these requirements, except to the extent that section 408 provides otherwise.[5] In this regard, it is well established that the failure to raise factual or legal issues during the comment period of a rulemaking constitutes waiver of the issues in further proceedings. *E.g., Forest Guardians v. U.S. Forest Service*, 495 F.3d

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[5] For example, section 408(d) allows the Agency to proceed to a final rule after publication of a submitted petition, rather than requiring publication of a proposal.

1162, 1170-1172 (10th Cir. 2007) (Claim held waived where commenters "failed to present its claims in sufficient detail to allow the agency to rectify the alleged violation"); *Nuclear Energy Institute v. EPA*, 373 F.3d 1251, 1290-1291 (DC Cir. 2004) ("To preserve a legal or factual argument, we require its proponent to have given the agency a 'fair opportunity' to entertain it in the administrative forum before raising it in the judicial forum.") *Native Ecosystems Council v. Dombeck*, 304 F.3d 886, 889-900 (9th Cir. 2002) (Purpose of requirement that issues not presented at administrative level are deemed waived is to avoid premature claims and ensure that agency be given a chance to bring its expertise to bear to resolve a claim); *Kleissler v. U.S. Forest Service*, 183 F.3d 196, 202 (3d Cir. 1999) (Policy underlying exhaustion requirement is that "objections and issues should first be reviewed by those with expertise in the contested subject area"); *National Association of Manufacturers v. U.S. DOI*, 134 F.3d 1095, 1111 (DC Cir. 1998) ("We decline to find that scattered references to the services concept in a voluminous record addressing myriad complex technical and policy matters suffices to provide an agency like DOI with a 'fair opportunity' to pass on the issue"); *Linemaster Switch Corporation v. EPA*, 938 F.2d 1299, 1305-1306 (DC Cir. 1991) (declining to consider in challenge to final rule, data alluded to in comments but not submitted during the comment period, and information submitted to EPA office that was not developing the rule).

Moreover, EPA clearly stated in the proposed rule that the Agency considered that the usual requirements applicable to informal rulemakings would remain applicable in this informal rulemaking. The

proposal explicitly noted that "[i]f you anticipate that you may wish to file objections on the final rule, you must raise those issues in your comments on this proposal. EPA will treat as waived, any issue not originally raised in comments on this proposal" (73 FR 44,865 (July 31, 2008)).

The fact that FFDCA section 408 in certain limited circumstances supplements the informal rulemaking with a hearing does not fundamentally alter the requirements applicable to informal rulemakings. Nor, as discussed below, does it convert this into a formal rulemaking, subject to the exception in section 553. The FFDCA section 408 establishes a unique statutory structure with multiple procedural stages, and delegates to EPA the discretion to determine the implementation that best achieves the statutory objectives. Accordingly, EPA interprets the notice and comment rulemaking portion of the FFDCA section 408 process as an integral part of the FFDCA process, inextricably linked to the administrative hearing. The point of the rulemaking is to resolve the issues that can be resolved, and to identify and narrow any remaining issues for adjudication. Consequently the administrative hearing does not represent an unlimited opportunity to supplement the record, particularly with information that was available during the comment period, but that commenters have chosen to withhold. For example, as discussed at greater length in Unit VI.E.2, both in their comments, and again in their objections, the Petitioners failed to provide the underlying mathematical modeling that supported their claim that the appropriate children's safety factor was 1X, rather than 4X. Instead, they presented only summary results. Similarly, although

the Petitioners claimed in their comments to have conducted an alternate analysis showing that aggregate carbofuran exposures to children would be safe, they failed to provide the data and details of that assessment to the Agency. They also failed to provide several critical components that served to support key inputs into that assessment.

To read the statute otherwise would be to render the rulemaking portion of the process entirely duplicative of the hearing, and thus, ultimately meaningless. *See, e.g., FDA v. Brown & Williamson Tobacco*, 529 U.S. 120, 132-133 (2000) (Court must interpret statute as a symmetrical and coherent regulatory scheme, and fit, if possible, all parts into a harmonious whole.) *APW, AFL-CIO v. Potter*, 343 F.3d 619, 626 (2nd Cir. 2003) ("A basic tenet of statutory construction * * * [is] that a text should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant, and so that one section will not destroy another * * *"), *quoting Silverman v. Eastrich Mulitple Investor Fund*, 51 F.3d 28, 31 (3rd Cir. 1995). The equities of this construction are particularly strong, where, as here, the information was (or should have been) available during the comment period. *See, Kleissler*, 183 F.3d at 202 ("[A]dministrative proceedings should not be a game or a forum to engage in unjustified obstructionism by making cryptic and obscure reference to matters that 'ought to be' considered and then, after failing to do more to bring the matter to the agency's attention, seeking to have that agency determination vacated") *citing Vermont Yankee Nuclear Power Corp. v. NRDC*, 435 U.S. 519, 553-54 (1978). For example, one of Petitioners' exhibits is the

drinking water modeling that served as the basis for the comments submitted on the proposed rule. The documents are dated well before the close of the comment period, and were clearly available for submission along with the comments (Exhibit 15). Yet they were only provided to EPA as part of the Petitioners' objections.

Contrary to Petitioners' contention, EPA's interpretation is entirely consistent with the FFDCA's language and structure. The fact that the statute and regulations allow "any person" to file objections is immaterial. At issue is not "who" may raise objections, but what issues may be raised as part of the objections to justify a hearing. And on the relevant question, the statute is clear that only certain issues—those of material fact—may be raised in objections to justify a hearing (21 U.S.C. 346a(g)(2)(B)). EPA's regulations expand on this limitation, providing, among other requirements, that hearings will not be held on legal or policy issues, nor on the basis of mere allegations, nor where EPA concludes that the data and information submitted, even if accurate, would be insufficient to justify the factual determination urged (*See* 40 CFR 178.32). It is true that FFDCA section 408(g)(2)(A) provides little guidance on the objections that a party may raise, requiring only that parties identify the specific provisions challenged, and state "reasonable grounds" for their objection. But the relative silence of the statutory provision does not mean that EPA is required to allow parties to raise any and all objections; rather it means that Congress left the question of what constitutes "reasonable grounds" for EPA to resolve.

In construing that requirement, EPA gives weight to the fact that 408(g) is only one part of a larger, multi-

stage, administrative process, and that the statute does not support an interpretation that this one phase be granted greater significance than the rest of the process. Also relevant is that Congress delegated broad discretion to the Agency to determine whether a hearing is "necessary" (21 U.S.C. 346a(g)(2)(B)). Accordingly, EPA believes that whether an objection states "reasonable grounds" is to be measured against the context of the rulemaking, and the provisions applicable to hearing requests.

Fundamentally, FFDCA section 408 delegates broad discretion to EPA, both to determine how best to harmonize the statutory process and to determine what constitutes "reasonable grounds" for objections. Consequently, the relevant question is whether EPA's exercise of discretion in requiring parties to present all available factual issues and evidence during the rulemaking is reasonable. It is undeniably a reasonable exercise of discretion to ensure that the rulemaking is not an opportunity for one party to waste the time and resources of all parties—both the government and other rulemaking participants—by failing to raise all of their issues or withholding information for the purpose of surprising the government at a later point during the proceeding. *See, e.g., Vt. Yankee*, 435 U.S. at 553-554; *United States v. L.A. Tucker Truck Lines*, 344 U.S. 33, 37 (1952) ("courts should not topple over administrative decisions unless the administrative body * * * has erred against objection made at the time appropriate under its practice").

EPA has consistently interpreted section 408 in this fashion since the 1996 amendments. For example, EPA previously ruled that a petitioner could not raise new issues in filing objections to EPA's denial of its

Original petition. *See* 72 FR 39318, 39324 (July 18, 2007) ("The FFDCA's tolerance revocation procedures are not some sort of 'game,' whereby a party may petition to revoke a tolerance on one ground, and then, after the petition is denied, file objections to the denial based on an entirely new ground not relied upon by EPA in denying the petition."). EPA reasoned that new issues were not cognizable because they "not an objection to the 'provisions of the * * * order [denying the petition]' " (Id.). Similarly, in a recent decision EPA denied NRDC's request for a hearing because they had failed in their original petition to raise the claim asserted in their objection (73 FR 42683, 42696 (July 23, 2008)). EPA noted that although NRDC did argue in its petition that EPA cannot make a safety finding without completing the endocrine screening program under FFDCA section 408(p), it did not assert claims regarding the endocrine data and the children's safety factor. Citing its previous decision, EPA denied NRDC's objections and hearing requests as to the children's safety factor (Id.). In that same decision, EPA also denied a number of hearing requests on the ground that requestor failed to proffer supporting evidence; EPA opined that a failure to offer evidence at an earlier stage of the administrative proceeding could not be cured by suddenly submitting such evidence with a hearing request. (*See* 73 FR 42683, 42710 (July 23, 2008) ("Presumably Congress created a multi-stage administrative process for resolution of tolerance petitions to give EPA the opportunity in the first stage of the proceedings to resolve factual issues, where possible, through a notice-and-comment process, prior to requiring EPA to hold a full evidentiary hearing, which can involve a substantial investment of resources by all parties taking part * * * Accordingly, if a party

were to withhold evidence from the first stage of a tolerance petition proceeding and only produce it as part of a request for a hearing on an objection, EPA might very likely determine that such an untimely submission of supporting evidence constituted an amendment to the Original petition requiring a return to the first stage of the administrative proceeding (if, consideration of information that was previously available is appropriate at all").

The two cases Petitioners cite that are specific to section 408(d) do not alter this assessment. Neither of those cases addressed the scope of the evidence that could be properly raised as part of objections to justify a hearing. Nor were the courts examining the extent of EPA's authority to impose requirements on the filing of objections under 408(g). Rather these courts were evaluating the scope of the FFDCA's exclusive review provisions, and whether the plaintiffs could bring a challenge to EPA policies and individual tolerance decisions without first exhausting the FFDCA's petition process. *Geertson Farms v. Johanns*, 439 F.Supp.2d 1012, 1022-1023 (N.D. Ca 2006); *NY v. EPA*, 350 F.Supp.2d 429, 442-443 (S.D.N.Y. 2004). This issue is not identical to the questions at issue here: for example, the court in *Geertson Farms* held that the plaintiffs' procedural and policy decisions were properly raised initially before the Agency through the petition process. 439 F.Supp2d at 442. Yet it is undeniable that EPA's regulations preclude the reliance on policy or legal issues as a justification for an Agency hearing.

Nor do the Petitioners' other cases compel a different result. The majority of the Petitioners' cases concern FFDCA section 701(e), which differs in several

significant respects from FFDCA section 408. Section 701(e) imposes no requirements whatsoever on the party submitting the objection: "any person may file objections * * * specifying the provisions of the order deemed objectionable, stating the grounds therefore * * *" 21 U.S.C. 371(e)(2). This section also expressly provides that FDA must hold a hearing upon request: "As soon as practicable after such request for a public hearing, the Secretary, after due notice, shall hold such a public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections." 21 U.S.C. 371(e)(3). In the face of this language, it is unsurprising that the courts held that FDA lacked discretion to deny a hearing. Further, under FFDCA section 701(e) the mere filing of an objection automatically stays the effectiveness of the challenged provisions. "Until final action is taken upon such objections is taken by the Secretary under paragraph (3), the filing of such objections shall operate to stay the effectiveness of those provisions of the order to which the objections are made." 21 U.S.C. 371(e)(3). By contrast, section 408 grants the Administrator the discretion to stay the effectiveness of the regulation if objections are filed. 21 U.S.C. 346a(g)(1). Indeed, the Petitioners' own cases specifically distinguish between section 701(e) and other FFDCA provisions. *See Pactra Industries v. Consumer Product Safety Commission*, 555 F.2d 677, 685 (9th Cir. 1977) (rejecting FDA argument that FFDCA section 701 should be read consistently with FFDCA sections 505 and 507 to allow for summary judgment procedures).

Petitioners' second argument is equally incorrect.[6] As an initial matter, the parties agree that FFDCA 408 establishes a hybrid rulemaking procedure, with informal rulemaking initiating, and frequently ending, the process (74 FR 23070 (May 15, 2009)); Obj at 62). Hybrid rulemaking is not formal rulemaking, which is the only rulemaking to which APA sections 556 and 557 apply. Nevertheless, Petitioners contend that once objections are raised, "Congress required the use of a formal rulemaking procedure involving an on-the-record hearing for resolving factual disputes." (Obj at 62) Nothing in the FFDCA section 408 or the APA supports this interpretation. And the cases cited in support of this argument are inapposite or misconstrued.

The APA section 553 on its face applies to all rulemakings except "[w]hen rules are required by statute to be made on the record after opportunity for an agency hearing" (5 U.S.C. 553(c)). Under this language, APA section 553 will apply unless two requirements are met: (1) The statute requires an opportunity for a hearing as part of the rulemaking, and (2) the hearing is required to be "on the record." FFDCA section 408 hearings are neither "required," nor mandated to be "on the record." The case law is clear that statutes containing both characteristics are the hallmark of formal rulemaking, and that formal rulemaking is the rare exception. *AT&T v. FCC*, 572

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[6] As discussed below, it is not clear that a determination that a hearing, if held, must be held in accordance with APA sections 556 and 557 precludes EPA from exercising its discretion to restrict the issues and evidence that may be raised at this final stage of the administrative process.

F.2d 17, 21-23 (2d Cir. 1978) ("The APA requires trial-type hearings only '[w]hen rules (or adjudications) are required by statute to be made (or determined) on the record after opportunity for an agency hearing.' ") (citations omitted); *Minden Beef Co v. Cost of Living Council*, 362 F.Supp. 298 (D. Neb. 1973) (examining whether statutory provision that "[t]o the maximum extent possible, the President or his delegate shall conduct formal hearings * * *" makes hearings mandatory, in determinating whether formal rulemaking required). *See also, e.g., Girard v. Klopfenstien*, 930 F.2d 738, 741 (9th Cir. 1991) ("The APA does not apply because a debarment hearing is not required by statute. The fact that the hearing is 'on the record' does not trigger an application of the formal adjudication provisions of section 554 of the APA"); *Smedberg Machine & Tool v. Donovan*, 730 F.2d 1089, 1092-93 (7th Cir. 1984) (holding section 554 inapplicable to a proceeding that "gives the adminsitrative law judge the discretion, rather than the obligation to conduct a review hearing."). As discussed below, in contrast to other sections of the FFDCA, such as section 701(e), FFDCA section 408 makes clear that a hearing is not mandatory upon request, but that EPA has broad discretion to determine whether a public hearing is necessary to receive factual evidence. *See*, 21 U.S.C. 346a(g)(2)(B), 346a(g)(2)(C). *See also*, H.R. Rep. No. 104-669, at 49 (1996).

The Supreme Court made clear in *Florida East Coast Railway v. FLRA*, that the circumstances under which rules are "required to be made on the record after opportunity for an agency hearing" are limited to those where Congress clearly indicates the intent to do

so. 410 US 224, 241 (1973). The mere fact that statute offers an opportunity for an agency hearing is not sufficient to bring rulemaking under scope of this exemption. Id. *See also, U.S. v. Allegheny-Ludlum Steel*, 406 U.S. 742 (1972); NRA v. Brady, 914 F.2d 475, 485 (9th Cir. 1990) (No oral hearing required where statute required Secretary to "afford interested parties opportunity for hearing" and Agency regulations reserved right to determine whether oral hearing warranted); *Wisconsin Gas Co v. FERC*, 770 F.2d 1144, 1165-1168 (DC Cir. 1985) (APA 556 hearing not required when statute only contained provisions requiring decision "after a hearing" and "substantial evidence" standard of judicial review); *AT&T v. FCC*, 572 F.2d 17, 21-23 (2d Cir. 1978) (APA 556 hearing not required when statute only contained provisions requiring decision "after a hearing" and "substantial evidence" standard of judicial review) *Philips Petroleum Co v. FPC*, 475 F.2d 842, 851-852 (10th Cir. 1973) (formal rulemaking not required even though statute required "full hearing" and Agency traditionally conducted trial-type adjudicative hearing).

Unless the statute providing for agency action prescribes "hearings on the record," either in those exact words or by using similar words to indicate that Congress specifically intended to impose the full trial-type requirements of sections 556 and 557, the statute does not fall within section 553's exception. *FL East Coast Railway*, 410 US at 241. While the absence of those words is not dispositive, "in the absence of these magic words, Congress must clearly indicate its intent to trigger the formal, on the record hearing provisions of the APA." *City of West Chicago, Illinois v. NRC.*

701 F.2d 632, 641 (7th Cir. 1983) (citations omitted). *See also, e.g., National Classification Committee v. ICC.* 765 F.2d 1146, 1150-1151 (DC Cir. 1985) ("Thus under *Florida East Coast*, there is a strong presumption that the procedural guarantees of section 553 of the APA are sufficient unless Congress specifically indicates to the contrary" *citing Vermont Yankee Nuclear Power Corp v. NRC*, 435 U.S. 519 (1978)); *AT & T v. FCC*, 572 F.2d at 21-23 ("The words, 'on the record' have become, as the District of Columbia Circuit has observed, a 'touchstone test' for the applicability of the APA's trial-type procedures"); *Philips Petroleum Co*, 475 F.2d at 851-852 ("The fact, as previously noted, that the Gas Act does not contain the words 'on the record' furnishes a strong argument in support of the Commission's contention that informal rulemaking satisfies the requirements of the APA"); *Minden Beef Co*, 362 F.Supp. at 306-307 ("Requiring 'formal hearings' is not identical with requiring that rules be made on the record after opportunity for agency hearing.") What is notable is that, in all cases, the court required clear expression that Congress specifically intended to impose full trial-type requirements.

Thus the question is whether Congress indicated any intent to entirely remove the FFDCA section 408 process from the requirements of 553. The mere fact that FFDCA section 408 requires some (or even many) of the procedures applicable under section 556 and 557 does not resolve the question. *See, e.g., National Classification Committee v. U.S.*, 765 F.2d 1146, 1150-1151 (DC Cir. 1985) (Rejecting argument that formal rulemaking required on grounds that "[u]nder Florida East Coast there is a strong presumption that the

procedural guarantees of section 553 of the APA are sufficient unless Congress specifically indicates to the contrary"); *Association of National Advertisers v. FTC*, 627 F.2d 1151, 1165-1168 (DC Cir. 1979) (formal rulemaking not required, even though statute "did order use of procedures not required in informal rulemaking" such as rights to rebuttal and cross-examination at public hearing.); *American Public Gas Association v. FPC*, 567 F.2d 1016, 1065-1067 (DC Cir. 1977) (Formal rulemaking not required by statutory provisions requiring "full hearing" and "substantial evidence" standard of judicial review).

In fact, the language and legislative history of section 408 provide clear indication of Congressional intent not to subject proceedings under these sections to APA sections 556 and 557. FFDCA section 408 does not reference APA sections 556 or 557 (see, *e.g.*, 7 U.S.C. 136d(c)(2)). By contrast, the previous version of section 408 did reference APA section 556, and the deletion of this requirement provides clear evidence of Congressional intent not to exempt FFDCA from APA 553. Prior to the 1996 amendments, section 408(d)(5) of the original act, which governed the conduct of hearings, specifically referenced APA 556. ("Any report, recommendations, underlying data, and reasons certified to the Secretary by an advisory committee shall be made part of the record of the hearing, if relevant and material, subject to the provisions of section [556] of the APA."). 21 U.S.C. 346(d)(5). Moreover, the previous version of the statute contained additional language consistent with the requirement of hearings subject to APA sections 556 and 557; for example, the previous version of section 408(d)(5) repeatedly makes reference to

"testifying at such hearing." A further consideration is that several other provisions of the FFDCA do explicitly reference APA sections 554 or 556. *Compare*, 21 U.S.C. 333(g)(3) ("A civil penalty * * * shall be assessed by the Secretary by an order made on the record after opportunity for a hearing provided in accordance with this subparagraph and section 554 of title 5"); 21 U.S.C. 342(f)(1)(C) (requiring the Secretary, upon any declaration of imminent hazard under this section to "initiate a proceeding in accordance with sections 554 and 556 of title 5"). The fact that Congress chose not to explicitly reference APA sections 556 or 557 provides a strong indication that they did not intend to impose such a requirement on section 408 proceedings. *See, e.g., St Louis Fuel and Supply Co v. FERC*, 890 F.2d 446, 449 (DC Cir. 1989) (holding that formal hearing under APA 554 not required on that grounds that "[w]e consider it significant that, unlike section 7193(c), other prescriptions in the DOE Organization Act expressly invoke the APA") (citations omitted).

Nor does any provision of FFDCA section 408 include the requirement that the hearing be "on the record." By contrast, several other provisions of the FFDCA include that exact phrase. *Compare*, 21 U.S.C. 335a(i) ("The Secretary may not take action * * * unless the Secretary has issued an order for such action made on the record after opportunity for an agency hearing on disputed issues of material fact."); 21 U.S.C. 335b(b)(1)(A) ("A civil penalty shall be assessed * * * by an order made on the record after an opportunity for an agency hearing * * *"); 21 U.S.C. 335(c)(b) ("The Secretary may not take action * * * unless the Secretary has issued an order for such action

made on the record after opportunity for an agency hearing on disputed issues of material fact.") Under all rules of statutory construction, those differences are presumed to be intentional. *Russello v. United States*, 464 U.S. 16, 23 (1983) ("[W]here Congress includes particular language in one section of a statute and omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion").

Equally significant is that the language of section 408 explicitly grants EPA broad discretion to deny a hearing. Section 408(g)(2)(B) provides that EPA shall "hold a public evidentiary hearing, *if and to the extent the Administrator determines that such a public hearing is necessary* to receive factual evidence relevant to material issues of fact raised by the objections" (21 U.S.C. 346a(g)(2)(B)) (emphasis added). This language grants EPA the discretion to determine whether the issues raised in objections are "material" issues of fact. Further, even where evidence relevant to an issue of material fact is proffered (essentially the standard set forth in 40 CFR 178.32), EPA construes the statutory language as requiring it to hold a hearing only where it determines it is necessary to receive proffered evidence. In other words, the statute grants EPA the discretion to determine that the issues could be resolved entirely on the basis of the existing written record. *See Philips Petroleum*, 475 F.2d at 848-849 (Formal rulemaking under APA 556 not required even though statute required that hearing be held, but "Commission has a very broad discretion in determining the form of its proceedings").

EPA's construction is confirmed by the House Commerce Committee Report accompanying the final bill, which states:

> New subparagraph (g)(2)(B) allows an objector to request a public evidentiary hearing. The Administrator would decide whether [a] hearing were necessary to receive factual evidence relevant to material issues of fact raised by the objections. The Committee expects EPA to use this discretion fairly and to grant hearings to responsible parties on all sides.

H.R. Rep. No. 104-669, at 49 (1996) (emphasis added). Notably, in an earlier version of the 1996 amendments, the House bill provided for a mandatory hearing during the notice-and-comment rulemaking stage of an EPA-initiated proceeding. [H.R. 1627, 104th Cong. Section 405 (new FFDCA section 408(e)(2)) ("EPA *shall provide* an opportunity for a public hearing * * *") (emphasis added). This requirement was dropped prior to enactment but the contrast with section 408(g)(2)(B) confirms the discretionary character of the latter.

If this were not sufficient indication of Congressional intent, further evidence is provided by the fact that in amending section 408, Congress chose not to adopt the provisions of section 701(e) that Petitioners cite in their objections. Clearly, Congress could have adopted the same provisions found in FFDCA 701(e), or in any of the other comparable FFDCA provisions discussed above, but chose not to do so.

EPA agrees that, when a hearing is warranted, the FFDCA requires an evidentiary hearing that comports with the procedures contemplated by 408(g)(2)(B). But

that is not the same as a requirement that section 553 be inapplicable to the proceedings, or that any hearing be held in accordance with APA sections 556 and 557.[7] Rather, section 408's provisions are consistent with APA sections 553 (b) and (c), which recognize the potential for hearings as part of informal rulemaking: "Except when notice or hearing is required by statute, * * * the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments, *with or without the opportunity for oral presentation*." 5 U.S.C. § 553(b)(c) (emphasis added).

Finally, Petitioners' citation to case law interpreting FFDCA section 701(e) does not compel a different result. Petitioners claim that the provisions of FFDCA 701(e) are "near identical" to those under section 408, and on this basis, argue that, "by analogy" these decisions compel an identical interpretation of the requirements of FFDCA section 408 (Obj at 65). Petitioners are correct that section 701(e) of the FFDCA has been held to be "one of those statutes, few in number, that does require rule-making hearings to be on the record in accordance with APA sections 556." *Pactra, supra*, 555 F.2d 677, 685 (9th Cir. 1977), *citing Florida East Coast Railway*, 410 U.S. at 237-38, (*dictum*). But in all other regards, Petitioners are incorrect.

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[7] EPA's regulations currently provide for a trial-type adjudicatory hearing. These regulations were adopted under the preceding statutory provision, and EPA has not yet undertaken any effort to revise the regulations to take into account the revised provisions of section 408.

As previously discussed, there are several significant differences between the statutory language of FFDCA sections 701 and 408 that render Petitioners' citation to these cases inapposite. Hearings are mandatory upon request under section 701, and the filing of objections operates to automatically stay the provisions of the rule. Section 701(e)(2) requires only that the objection "state the grounds therefore," rather than requiring the a statement of "reasonable grounds." *See Pactra* at 684 (distinguishing FFDCA section 701(e) from 507(f) because the latter requires hearing applicants to show 'reasonable grounds'). Further, although section 701 does not itself contain the requirement that the hearing be "on the record," the legislative history of this provision indicates that Congress intended such hearings to be "on the record." *Pactra*, 555 F.2d at 682-684 (detailing FFDCA section 701 legislative history). These characteristics played a significant role in the court's decision that FDA lacked the authority to deny hearings under section 701(e) on the basis of summary judgment proceedings.[8] However, as shown above, the legislative history of section 408 provides a clear indication of a contrary Congressional intent with respect to hearings under this section.

Petitioner's reliance on the "substantial evidence" standard in FFDCA section 408(i) is equally misplaced. Incorporation of that standard into judicial review

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[8] Contrary to Petitioners' allegation, the DC Circuit has not "arrived at the same conclusion" (Obj at 65). All of the discussion from *Independent Cosmetic Manufacturers and Distributors v. U.S. Dept of Health, Education, and Welfare* presented in their objections is dicta from a dissenting opinion. 574 F.2d 553, 572 (DC Cir. 1978).

provisions alone has been consistently held to be insufficient to indicate Congressional intent to impose the full requirements of APA sections 556 and 557 to a rulemaking. *Wisconsin Gas Co v. FERC*, 770 F.2d at 1167 ("The procedures required to develop this 'substantial evidence' are not necessarily the strict adversary procedures of sections 556 and 557 of the Administrative Procedures Act"); *Public Systems v. FERC*, 606 F.2d 973, 979, n. 32 (DC Cir. 1979) (substantial evidence requirement in Natural Gas Act "carries no implications for procedures to be followed by the Commission in compiling the record"); *American Public Gas Association v. FPC*, 567 F.2d 1016, 1065-1067 (DC Cir. 1977) ("In our view, however, this requirement [of the substantial evidence standard] in the judicial review provision of the Act does not dictate the procedure to be followed, or the nature of the hearing to be held).

The specific language of 408(i) defines the standard for the reviewing court; it does not describe the process by which the agency hearing is to be conducted. This is quite different from the language under 501(c) of the CWA, on which the DC Circuit relied in holding that hearings pursuant to APA section 554 were required. *Marathon Oil v. EPA*, 564 F.2d 1253, 1262-1265 (DC Cir. 1977). The CWA section 501(c) states "[i]n any judicial proceeding * * * in which review is sought of a *determination under this chapter required to be made on the record after notice and opportunity for a hearing* * * *" 33 U.S.C. 1369(c) (emphasis added). By contrast, FFDCA section 408(i) merely provides that "[a]s to orders issued following a public evidentiary hearing, the findings of the Administrator with respect to questions of fact *shall be*

*sustained if supported by substantial evidence when considered on the record as a whole*" (21 U.S.C. 346a(i)) (emphasis added). It is also worth noting that the court expressly distinguished this case, which dealt exclusively with an adjudicatory proceeding, from those circumstances in which an agency proceeds through rulemaking. 564 F.2d at 1262, n. 30.

In any event, even if section 556 did apply to hearings under section 408, Petitioners cannot avoid the case law under section 553 and EPA's interpretation of the interrelationship between any hearing granted under section 408(g)(2) and the rulemaking preceding it. Petitioners cite to the general evidentiary provision in section 556(d) that provides that only irrelevant or immaterial evidence may be excluded and argue that this generic standard necessarily defines the scope of a hearing regardless of the statutory scheme in which it is embedded. However, context matters. As the DC Circuit noted, "the informal procedures of section 553 of the APA and the more formal requirements of sections 556 and 557 are not mutually exclusive." *American Public Gas Association*, 567 F.2d at 1067. Even the caselaw relied upon by Petitioners does not suggest that section 556(d)'s evidentiary provision trumps all other considerations. Petitioners cite primarily to *Catholic Medical Center, Inc. v. NLRB*, 589 F.2d 1166, 1170 (2d Cir. 1978). In that case, the Second Circuit interpreted section 556(d) as specifying that "an agency thus may not provide for the exclusion of evidence *not protected by a privilege or countervailing policy.* * * *" Id. (emphasis added). Here, EPA has interpreted its authority to impose such a countervailing policy. Moreover, EPA's interpretation is clearly within the

broad discretion granted it by the statute and the policy underlying the interpretation is a reasonable adaptation of judicial practice with regard to issues not presented in notice and comment rulemaking proceedings. Thus, Petitioners' technical and formalistic argument concerning section 556(d), which ignores the context of the section 408(g)(2) hearing provision, must be rejected.

Similarly unavailing is Petitioners' argument concerning section 556(e)'s specification that the "exclusive record for decision" after a hearing is material or testimony submitted in the hearing or hearing proceeding. Petitioners assert that this provision somehow removes any limitations on what can be submitted at the hearing because "that 'exclusive record' is independent of whatever record may exist in the prior informal rulemaking * * *." (Obj at 64). Yet the hearing record is not "independent" of the rulemaking record in that EPA regulations require that the rulemaking record be included in the record of the hearing (40 CFR 179.179.83(a)(1)). Once again, Petitioners' argument fails because it considers section 556 in isolation rather than taking into account the context of the entire administrative proceeding in which the hearing is embedded.

Finally, Petitioners complain that EPA "raised a host of new issues and assertions for the first time in the Final [rule]," and it would be inequitable for EPA to prevent them from raising objections on these new assessments. Petitioners identify ten categories of "new computations and contentions" that they claim raise issues that go beyond those addressed in their prior comments. With one exception, all of these "new computations and contentions" were revisions to

analyses conducted in response to Petitioners' comments. Indeed, some of these were revisions undertaken in response to Petitioners' specific request; for example, the "new" BMD analyses they identify were: (1) Corrections made in response to an EPA error identified in their comments; (2) an extrapolation of $BMD_{50}$ s, using the dose-time-response model, to develop a common point of comparison between all studies, which they had claimed was the appropriate approach; and (3) a calculation generating a new dose-response model in order to calculate the $BMD_{50}$ s for brain and RBC AChE inhibition, in response to Petitioners' claim that failure to do so was inappropriate (Refs. 24, 25, 85). Since these analyses were done at their behest, they can hardly complain that they present new issues on which they had no opportunity to comment. The Agency's underlying methodologies were the same as those used for the proposed rule; the analyses were based on information provided by the Petitioners and/or to address the revisions requested as part of the Petitioners' comments.

Regarding the remaining analyses: The "new exposure estimates for ground and surface water," as well as the "revised dietary risk and drinking water assessments" and "new assessment of the impact of buffers and setbacks" were conducted to accurately reflect the use under the registration, as modified by FMC's cancellation of uses and additional mitigation measures. The same is true for the "new analysis of the various carbofuran labels;" the analysis related to the labels submitted as part of the September 2008 comments. The chlopyrifos studies were raised in response to the Petitioners' citation to a subset of

chlorpyrifos data. They acknowledge that the "new literature citations" were provided to address one of their contentions (Obj at 56). The sole exception relates to EPA's calculation of carbofuran-specific half-lives for use in the dietary risk assessment. As discussed in Unit VI.G.2, EPA does not reject Petitioners' challenge to EPA's calculation of the 186-minute half-life on the basis that it is untimely.[10]

A fair indication that EPA has not raised a host of new issues in the final rule is that, with the exception of the revised half-lives, Petitioners do not challenge the substance of any of the allegedly "new" information. Indeed, as discussed in the sections below, Petitioners have in many instances failed to address any of the explanations or revised analyses EPA presented in the final rule.

Ultimately, Petitioners' complaint misses the point. EPA does not interpret the statute and regulations to preclude the submission of any new information as part of the objections phase. Such a position would in fact be inconsistent with EPA's own regulations and past practice, which require that in order to support a hearing request, a party submit more than "mere allegations or denials" (40 CFR 178.32(b)(2)). Rather, EPA's interpretation in this regard is analogous to the determination of whether a final rule is the logical outgrowth of the proposal and the comments. For example, EPA does not reject Petitioners' citation to new studies in support of the contention that RBC

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[10] The Petitioners' claim that "EPA provided new information concerning the raw data collected and records maintained by ORD in relation to its toxicology studies" is inaccurate. EPA provided no new information on this topic in the final rule.

AChE data are generally more sensitive than PNS tissues on the grounds that they are untimely. This is because these studies are simply more evidence supplementing the issue they fairly raised in their comments, and are intended to rebut EPA's response in the final rule. Similarly, the submission of new analyses relating to the ground water pH in Exhibit 14 is not considered untimely, as the issues they raise relating to ground water pH were fairly raised in comments and discussed throughout the rulemaking. Ultimately, EPA's policy is merely that the objections phase does not present an opportunity for parties to begin the process entirely anew, by raising issues or information that could have been fairly presented as comments on the proposed rule. Nor is the statute's additional procedural step an excuse to withhold information that was clearly available at the time of the rulemaking.

2. *Implications for FMC's Submission of New Registration Amendments as Part of their Objections.* On June 29, 2009, in conjunction with their objections on the final rule, FMC Corporation submitted a request for EPA to amend its registration in several regards. Some of the requested amendments were further mitigation measures intended to address carbofuran's dietary risks. The most significant of these was a proposal intended to ensure that only 2% of any watershed would be treated with carbofuran. The proposal would require that, within five days of applying the product, all applicators report to FMC the following information: The location that the product will be used, crop, use rate, application method, acreage, and quantity applied. Based on this information, FMC would track the percentage in each

watershed. "Whenever it appears that carbofuran has been applied to 1.75% of any watershed," the registrant would report that information immediately to EPA, "cease further sales in any county that overlaps with such a watershed for that use season, and shall attempt to recall all unused carbofuran within such counties by offering to repurchase such unused product" (Exhibit 2). Additionally, FMC requested that its registration be amended to require that "based on watershed boundaries, FMC * * * prior to each use season, allocate to its distributors in a manner which will attempt to ensure that no distributor receives more carbofuran for sale than can be accommodated by the 2% watershed area cap in any watershed supplied by that distributor."

In addition, FMC proposed to add geographic restrictions that would prohibit use in certain parts of the country. Specifically, they proposed to restrict the use of carbofuran on potatoes to the three states: Idaho, Oregon, and to select counties in Washington. They proposed to restrict use on Sunflowers to only Colorado, Kansas, Nebraska, and South Dakota, as well as limited portions of North Dakota and Oklahoma. Under this proposal, use on corn would be restricted to Colorado, Iowa, Illinois, Indiana, Kansas, Missouri, Nebraska, and limited counties in Wisconsin. Further, they proposed to add set-backs (*i.e.*, areas where carbofuran could not be applied) ranging between 100 and 1,000 feet from drinking water wells, depending on the geographic area. Finally, as part of these amendments, FMC also requested that EPA revise its registration to permit use of carbofuran on pumpkins in Ohio, Illinois, and Indiana, and to cancel the use on pumpkins in the southeastern United States.

As made clear in Unit VI.C., FMC's newly-proposed registration amendments are irrelevant to the prior determinations made in the final tolerance revocation rule. Further, as discussed in Unit VI.D., as a consequence of the failure to raise these amendments measures as part of their comments on the proposal, EPA considers that all issues arising exclusively as a result of these proposed amendments have been waived. There is no evident reason that FMC could not have offered these amendments as part of its September 2008 proposals. All of the information on which they rely was available in September of 2008. All of the risk concerns that the amendments were intended to address were discussed at length in EPA's proposed rule. Since 2006, EPA has clearly stated its determination that carbofuran's potential to leach into ground water and to runoff into surface water caused unacceptable dietary risks. EPA's methodologies for evaluating these risks have not changed since 2006. Indeed, EPA deferred regulatory action for several months, subsequent to the Agency's determination in 2006 that carbofuran did not meet either the FIFRA or FFDCA standard, to allow the Petitioners time to generate data to address the exact same issues these proposals are intended to address. In their comments on the proposed rule, Petitioners provided some mitigation measures intended to address issues relating to the carbofuran's leaching and runoff potential: Well set-backs, buffers, geographic use restrictions, and aerial application recommendations.

As previously discussed, EPA provided clear notice in the proposed rule that issues that that were not raised during the comment period would be considered waived in subsequent stages of the administrative

process (73 FR 44,865). Petitioners were well aware of this, as they commented that "EPA's requirement to raise all issues in the comments does not appear to be legally binding" (Ref. 18 at 118). Indeed they acknowledged that they "agree that identifying disputed issues in the comments is efficient and desirable, and may help to narrow the issues arising in subsequent objections and an administrative hearing. Therefore, the commenters have made a good faith attempt to raise in these comments the principal issues of which they are aware" (Id.).

At this stage of the process, the statute requires the Petitioners to object to the conclusions and provisions in EPA's final rule, not to propose some new alternate license that they claim would meet the statutory standards (21 U.S.C. 346a(g)(2)(A) ("any person may file objections * * * specifying with particularity the provisions of the regulation * * * deemed objectionable"). In fact, one might fairly read their proposal as an admission that the existing license fails to meet the statutory standards.

A further consideration is that the question of whether these amendments can be approved depends on whether the Agency eventually determines the amended registration meets the standards of FIFRA, which include considerations beyond the dietary risks evaluated under the FFDCA. Under FIFRA, the Agency's review of the amendments is also subject to a statutorily mandated schedule (established as part of the Pesticide Regulatory Improvement Act (PRIA)). These are no small matters. In terms of timing, FMC explicitly acknowledged in its letter submitting the proposed amendments that the amendments were subject to the PRIA review process, requesting that

the actions be subject to the PRIA 8-month statutory deadline (which would establish a statutory deadline of February 2010 for Agency consideration of FMC's application). It is not clear whether FMC is arguing that its application be accorded a higher priority than other applications and be taken out of turn, or whether FMC is arguing that the consideration of the objections and request for hearing must be delayed until the FIFRA review process is completed. EPA rejects either position; Petitioners cannot use this tolerance proceeding to evade FIFRA's statutory review scheme, or use that scheme to delay this tolerance proceeding.

As noted, although FIFRA incorporates the FFDCA dietary risk standard, FIFRA also requires the Agency to evaluate a much wider scope of issues in determining whether to grant new license requirements. For example, EPA must evaluate the impact this proposal would have on worker and ecological risks. In addition, EPA must carefully evaluate the policy implications involved in authorizing Petitioners' scheme. In this regard, it is worth noting that FMC's scheme is a novel one that raises significant policy questions that are specific to FIFRA, such as whether the steps proposed could be adequately enforced, which could affect the confidence that everybody would, in fact, comply with all the steps, (e.g., who would investigate whether users have properly notified FMC of use of the product; would users have to keep records to demonstrate to inspectors that they had appropriately reported use; how would further sales in a county be prohibited); and whether the steps themselves are appropriate tools from a policy perspective for dealing with risks

associated with the use of a pesticide (*e.g.*, is it appropriate to require users to report use to a pesticide manufacturer; is such reporting subject to approval under the Paperwork Reduction Act; is it appropriate public policy to limit sales in a watershed so that some growers may have preferential access to a product; would the scheme encourage early and potentially unnecessary purchase of product by users; under what circumstances, if any, should EPA approve label and license conditions that require the extra vigilance that would be required here of users, distributors, and state and federal regulators). Even if this scheme were determined independently to meet the FFDCA safety standard, if ultimately EPA were unable to grant the amendment based on the other considerations that it must evaluate under FIFRA, the unacceptable dietary risks would still remain. Thus, whether this scheme could result in a determination that the dietary risks are acceptable is not ultimately severable from the larger FIFRA process. Nor would it be appropriate to attempt to resolve FIFRA issues in a hearing under the FFDCA.

Indeed it is questionable whether consideration of the proposed amendments would be appropriate even under Petitioners' position that all objections made in good faith may be presented at this stage of the proceeding (Obj at 61). For example, less than six months prior to their recent submission, the Petitioners proposed voluntarily cancellation of all use on pumpkins except in the Southeastern United States, alleging that sales data demonstrated that carbofuran was needed in the Southeastern U.S. In response to this amendment, which was submitted as part of their comments on the proposed rule, EPA analyzed the

dietary risks based on this proposed use pattern for the final rule. A request, mere months later, for additional use on pumpkins in states with different geographic and weather conditions and cancellation of the use in the Southeastern U.S., may fairly be considered suspect—an action intended to delay the revocation process by forcing the Agency to conduct yet additional analyses, rather than a good-faith objection.

For all of these reasons, EPA has determined that reliance on these proposed amendments as a basis for raising objections to the final rule, or for requesting a hearing is not appropriate. Nevertheless, EPA evaluated the individual objections premised on the newly requested terms and conditions of registration. And in each case, the submitted materials relating to these objections and hearing requests independently failed to meet the statutory and regulatory requirements to justify a hearing, as discussed in the Units below.

*E. Response to Specific Issues Raised in Objections and Hearing Requests Relating to EPA's Children's Safety Factor*

To more fully understand Petitioners' objection and hearing request with regard to EPA's choice of a 4X children's safety factor and EPA's responses, a little background is helpful. Section 408 of the FFDCA imposes a default additional safety factor for the protection of infants and children, to take into account the fact that children are frequently more sensitive to a pesticide's effects than adults. This default 10X safety factor can only be revised if the Agency has "reliable data" to demonstrate that the alternative safety factor-or no safety factor-"will be safe for infants and children" (21 U.S.C. 346a(b)(2)(C)). In determining

whether a different factor is safe for children, EPA focuses on the three factors listed in section 408(b)(2)(C)—the completeness of the toxicity database, the completeness of the exposure database, and potential pre- and post-natal toxicity. In examining these factors, EPA strives to make sure that its choice of a safety factor, based on a weight-of-the-evidence evaluation, does not understate the risk to children. (Ref. 79). The Agency's approach to evaluating whether sufficient "reliable" data exist to support the reduction or removal of the statutory default 10X is described below in Figure 1.

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[Figure 1 omitted]

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EPA has consistently required that data comparing the AChE inhibition in young rat pups (typically PND11) and adult rats be submitted on AChE-inhibiting pesticides, such as carbofuran, to determine the extent of children's potential sensitivity. The study measures the levels of AChE inhibition in both potentially relevant target tissues: The brain and either the PNS or red blood cell (RBC), which serves as a surrogate for the PNS. EPA required these data from FMC for carbofuran, and FMC on two occasions submitted the studies. Both sets of data, however, were rejected by EPA as scientifically flawed because they inaccurately measured the levels of RBC AChE.

Despite the invalidity of the two FMC studies as to RBC AChE, EPA still has certain, limited RBC AChE data and other PNS-related data on carbofuran from other studies. These other carbofuran data indicate the following: (1) PNS-related effects (tremors) occur in pups as a result of exposure to carbofuran at low doses;

(2) juveniles are more sensitive than adults to carbofuran based on brain measures; (3) juveniles are more sensitive than adults to carbofuran based on RBC AChE measures; and (4) the relative sensitivity of juveniles compared to adults as to RBC AChE is significantly greater the relative sensitivity of juveniles compared to adults as to brain AChE. It is also noteworthy that the data in adult rats showed RBC AChE was generally more sensitive to carbofuran's effects than brain AChE (RBC AChE inhibition was higher than brain at every dose except the lowest), although these data are of limited relevance, because they were conducted on adult animals rather than pups, and adult responses are frequently not predictive of children's responses. However, because the available pup RBC AChE data from EPA-ORD did not involve testing at doses that produced a sufficiently low level of inhibition, the data were not sufficient to develop a PoD for juveniles based on RBC AChE.

Accordingly, in making its children's safety factor determination for carbofuran, EPA was faced with three significant issues: (1) Sufficient data on carbofuran that are routinely-required for AChE-inhibiting pesticides to measure PNS effects was not available; (2) available data measuring the levels of AChE inhibition in brain and RBC indicated that juveniles were more sensitive than adults to carbofuran and other carbofuran data indicated that PNS-related effects could occur in pups at low dose levels; and (3) although the evidence on carbofuran as to RBC AChE inhibition in juveniles indicated that effects on juveniles' PNS might be the most sensitive endpoint, there was not sufficient data to calculate a

PoD (for use in determining the safe dose or PAD) on these effects. Despite the incompleteness of the toxicity database and the evidence indicating the potential for pre- and post-natal toxicity at a very sensitive level, which indicate the need to retain a children's safety factor, EPA nonetheless determined that, because there was limited reliable data in juveniles, a full statutory default 10X was not necessary to ensure that children's exposures would be "safe." EPA undertook a complex comparison of the brain and RBC AChE data in juveniles and determined that the likely increased level of sensitivity for RBC AChE inhibition is 4X. EPA thus concluded that using an additional children's safety factor of 4X applied to the PoD from data on brain AChE inhibition in juveniles would protect infants and children.

*1. Challenge to EPA's Scientific Basis for Retention of a 4X Children's Safety Factor.* Petitioners object to EPA's conclusion that the lack of peripheral tissue data justifies retention of any portion of the children's safety factor. Petitioners raise two claims in this regard. First, they allege that a carbofuran PoD based on brain AChE is adequately protective of PNS effects. Second, they claim that RBC AChE inhibition data are not the best surrogate for PNS effects when brain data are available, and therefore, these data are not an "appropriate surrogate for PNS effects" and should not have been relied upon as the basis for retaining any portion of the safety factor. In support of these points, Petitioners submit summaries of the testimony they intend to offer at a hearing, along with copies of published studies that they allege provide evidence of the points raised in the testimony.

In essence, these two main issues overlap, particularly with respect to the evidence submitted. Petitioners rely on the same studies to support both points. However, they are presented below separately as discrete issues in the interest of clarity. Supplemental to these two main points, EPA has identified three separate allegations made by Petitioners in support of this objection, which are also analyzed individually in this section.

a. *Objection/hearing request subissue: Whether a carbofuran PoD based on pup brain AChE inhibition data alone is adequately protective of PNS effects.* Petitioners argue that by establishing the PoD on pup brain AChE inhibition data, EPA has adequately accounted for all PNS effects in pups without the need for an additional children's safety factor. They argue that brain data will adequately protect against PNS effects, based on the claim that the available data show that the brain is equally sensitive or more sensitive than PNS tissue. In support of this objection, Petitioners' submit the evidence contained in Exhibits 4 and 6. Exhibit 4 consists of a report by Kendall Wallace, PhD, entitled "Expert Report: Carbofuran FQPA Safety Factor," along with published studies conducted with OP chemicals, and other NMC chemicals (Ref. 17, 51, 53, 54, 59, 61, 62, 72). Exhibit 6 consists of a report by Lucio Costa, PhD, entitled, "Expert Report: Carbofuran's FQPA Safety Factor and Interspecies Uncertainty Factor," as well as published literature studies conducted with chlorpyrifos and disulfoton, both OP pesticides, and a single study with propoxur, an NMC pesticide.

*i. Background.* In the proposed tolerance revocation, EPA presented its rationale for retention of a children's safety factor.

As explained in Unit IV.A, EPA uses a weight of evidence approach to determine the toxic effect that will serve as the appropriate PoD (or regulatory endpoint) for a risk assessment for AChE inhibiting pesticides, such as carbofuran (Ref. 78). Neurotoxicity resulting from carbofuran exposures can occur in both the central (brain) and peripheral nervous systems (PNS). In its weight of the evidence analysis, EPA reviews data, such as AChE inhibition data from the brain, peripheral tissues and blood (*e.g.*, RBC or plasma), in addition to data on clinical signs and other functional effects related to AChE inhibition. Based on these data, EPA selects the most appropriate effect on which to regulate; such effects can include clinical signs of AChE inhibition, central or peripheral nervous tissue measurements of AChE inhibition or RBC AChE measures (Id). Due to the rapid nature of NMC pesticide toxicity it is difficult to document effects in the PNS or even AChE inhibition in the PNS and thus studies measuring AChE inhibition in the PNS are very rare for NMC pesticides. Although RBC AChE inhibition is not adverse in itself, EPA's policy is to use it as a surrogate for inhibition in peripheral tissues when peripheral data are not available. As such, RBC AChE inhibition provides an indirect indication of adverse effects on the nervous system (Id.).

There are laboratory data on carbofuran for cholinesterase activity in plasma, RBC, and brain from studies in multiple laboratory animals (rat, mouse, dog, and rabbits). Among these are three studies that compare the effects of carbofuran on PND11 rats with

those in young adult rats (*i.e.*, 'comparative AChE studies') (Refs. 1, 2, 66). Two of these studies were submitted by FMC and one was performed by EPA-ORD. An additional study conducted by EPA-ORD involved PND17 rats (Ref. 63).

The studies in juvenile rats show a consistent pattern that juvenile rats are more sensitive than adult rats to the effects of carbofuran. These effects include inhibition of brain AChE in addition to the incidence of clinical signs of PNS neurotoxicity, such as tremors, at lower doses in the young rats. This pattern has also been observed for other NMC pesticides, which exhibit the same mechanism of toxicity as carbofuran (Ref. 81). The 2008 SAP, in its review of the carbofuran draft NOIC, concurred with EPA that the brain AChE data clearly indicate that the juvenile rat is more sensitive than the adult rat (Ref. 36).

The Agency does not have any AChE inhibition data for carbofuran in the PNS tissue of adult or juvenile animals. There is data on RBC AChE inhibition, which is a surrogate for PNS tissue AChE inhibition, in adult animals at both high and low doses, and RBC data in pups, but only at doses causing greater than 50% AChE inhibition (a very high level of inhibition). In adults, the data show that RBC is generally more sensitive to the effects of carbofuran than the brain, but that at the lowest dose tested, brain and RBC have similar sensitivity. In pups, the available data at higher doses show that, like adults, RBC is more sensitive than brain. For example, the EPA-ORD studies showed that RBC AChE inhibition is more sensitive than brain AChE inhibition in both PND11 and PND17 pups at the lowest dose tested. However, the lowest dose (0.1 mg/kg) in both studies

missed the lower portion of the RBC AChE inhibition dose-response curve for pups. At the lowest dose, PND 11 pups had approximately 40% brain and 53% RBC AChE inhibition while PND17 pups had approximately 25% brain and 50% RBC AChE inhibition. Consequently, the Agency does not have RBC AChE inhibition data in pups at the low doses (*i.e.*, those that cause only 10% inhibition) that are relevant to risk assessment to serve as a surrogate for PNS tissue data.

EPA explained that additional evidence for the sensitivity of the PNS to carbofuran's effects comes from data in pregnant rats exposed to carbofuran that showed clinical signs that may be indicative of peripheral toxicity. Finally, EPA explained that data from other AChE inhibiting pesticides show that direct measures of peripheral nervous system (*e.g.*, lung, heart, and liver AChE) can be more sensitive than brain AChE inhibition. To help illustrate, EPA gave an example of another chemical for which brain inhibition alone was not at all predictive of toxicity, to help explain why the lack of carbofuran data was so significant. The example given was fenamiphos (an OP pesticide), where cholinergic toxicity (*e.g.*, tremors, miosis, salivation) was observed following inhibition of RBC, but not brain, even up to maximally tolerated doses (McDaniel and Moser, Ref. 53).

Normally, EPA would regulate based on the most sensitive endpoint, which in this case would appear to be the effects on children's PNS. However, as discussed above, EPA lacked the information that would allow it to establish a PoD (or regulatory endpoint) based on the effects on children's PNS. EPA therefore established its PoD based on the AChE

inhibition in pup brain. Generally, by regulating based on pup data, EPA would directly account for any additional sensitivity that children might have, because the safe levels estimated from these data would be the levels at which infants and children would be affected. In such circumstances, EPA could reduce the children's safety factor.

But because EPA lacked the data on the PNS effects in pups at low doses of carbofuran, which are most analogous to the exposures that infants and children will receive from eating food with carbofuran residues, the Agency could not be confident that assessing risk using brain AChE inhibition would be protective of potential effects in the PNS for infants and children. Accordingly, EPA determined that, even though the Agency was relying on pup data, consistent with the statutory mandate that an additional safety factor be applied to account for children's increased sensitivity in the absence of information affirmatively demonstrating that no such safety factor is necessary, the Agency could not conclude that removal of the statutory default 10X would be "safe for infants and children." As some information was available to characterize the effects on infants and children, EPA concluded that the full default 10X was unnecessary, and that it could safely reduce the factor to 4X.

Petitioners raised many of the same assertions in their comments on EPA's proposed rule that they raise in their objections. For example, the Petitioners claimed that because EPA relied on pup brain data, no additional safety factor would be necessary to account for children's increased sensitivity, because "brain data are a better surrogate for the PNS than RBC data." The comments also contended that RBC data are

problematic in a number of regards, *e.g.*, they are more variable. They also argued that EPA had generally relied exclusively on brain data for other NMC pesticides, and that to require an additional safety factor for carbofuran based on the lack of RBC AChE data was inconsistent with those other decisions.

In the final rule and response to comments EPA responded to all of the Petitioners' claims, and comprehensively restated its reasoning that the lack of PNS inhibition data warranted retention of some portion of the children's safety factor for carbofuran (74 FR 68694-68695 (May 15, 2009)). In essence, EPA explained that Petitioners had not presented any information that fundamentally altered the available risk information before the Agency. Specifically, EPA concluded that, given that (1) the EPA-ORD data clearly show that a surrogate measure of the peripheral nervous system (RBC AChE) in juvenile rats is more sensitive to the effects of carbofuran than brain AChE inhibition; (2) clinical signs consistent with toxicity to the peripheral nervous system were seen at very low doses of carbofuran; and (3) data from other AChE inhibiting pesticides show that direct measures of peripheral nervous system (*e.g.*, lung, heart, and liver AChE) can be more sensitive than brain AChE inhibition, the Agency could not be confident that assessing risk using brain AChE inhibition would be protective of potential effects in the peripheral nervous system for infants and children.

ii. *Denial of hearing request.* EPA is denying Petitioners' hearing request on this subissue because the evidence proffered, even if established, is insufficient to justify the factual determination urged (40 CFR 178.32(b)(2)). The totality of the evidence

submitted fails to demonstrate a reasonable possibility that exclusive reliance on carbofuran brain data will be protective, largely because they have failed to proffer any evidence on several points that are critical to their argument. As such, the objection rests on speculation and mere allegation, and a hearing will not be granted on this basis (Id. See, e.g., 73 FR 42708 (July 23, 2008); 57 FR 6667, 6671 (February 27, 1991)).

It is important to remember that to obtain a hearing on EPA's children's safety factor decision, Petitioners must proffer more than evidence on whether EPA erred, Petitioners must proffer evidence showing there is "reliable data" supporting the children's safety factor they urge. Without the latter, their objection is immaterial because the default position is retention of an additional 10X safety factor. Accordingly, EPA has evaluated Petitioners' proffers on its children's safety factor claims in terms of whether they are sufficient to provide the "reliable data" needed to justify the 1X safety factor that Petitioners propose.

For purposes of resolving whether the statute requires the retention of a children's safety factor, the critical issue is whether sufficient data exists to determine the effects on children's peripheral nervous systems from low doses of carbofuran. None of the evidence submitted affirmatively addresses this question. As discussed in more detail below, the only evidence proffered in support of this objection was: (1) A subset of the available carbofuran data from adult animals; and (2) data, primarily in adult animals, from other chemicals to demonstrate that generally, reliance on brain data will be protective of PNS effects, and therefore EPA can assume that the same will hold true

for carbofuran. However, the Petitioners have failed to submit any data to demonstrate that the effects seen in adults will be predictive of the effects in juveniles. They have also submitted no evidence specific to carbofuran that demonstrates the effects of low doses on children's peripheral nervous systems. This is critical because the evidence they do proffer on other chemicals fails to establish that as a general matter, reliance on brain data will always be protective of the effects on the PNS. The majority of the evidence in other chemicals actually proves that reliance on brain data is frequently not protective of the effects on the PNS. And the remainder of the evidence on this point, taken in the light most favorable to the Petitioners, provides only equivocal support for Petitioners. Such evidence, by itself, is insufficient to relieve the uncertainty that remains with respect to carbofuran, based on the affirmative evidence in carbofuran-specific data, showing that reliance on brain data may not be protective. And such evidence, that entirely fail to address the points that the statute makes central to a determination of the appropriate children's safety factor, cannot justify a hearing.

When examined more closely, their overall evidentiary proffer is even less impressive. As discussed, much of the evidence was conducted in adult rats. Indeed the only evidence Petitioners submitted in support of this objection that was specific to carbofuran's effects on the PNS was data in adult rats. No evidence was submitted to demonstrate that adult data are generally predictive of responses in pups. Nor was any evidence submitted to support the assumption that pups will respond to low doses of carbofuran in the same way as adults. Thus their evidentiary proffer is

effectively based on mere speculation that adult data will be predictive of pup responses, which cannot justify a hearing (40 CFR 178.32(b)(2)). As EPA previously explained in the proposed and final rules, responses in adult rats are not necessarily predictive of, or relevant to, responses in juveniles since the metabolic capacity of juveniles is less than that of adults (73 FR 44864, 74 FR 23046). As such, juvenile rats can be more sensitive to some toxic agents. Simply put, studies that only involve adult animals, therefore, do not provide information on effects on the young, which is the focus of the children's safety factor. No matter how much evidence Petitioners can amass showing that brain AChE is protective of RBC AChE in adult animals, that does not relieve the uncertainty concerning potential sensitivity of PNS tissues in juvenile animals, particularly when all of the existing carbofuran data shows that pups are more sensitive than adults to the effects of carbofuran, and that clinical signs consistent with toxicity to the PNS were seen in pups at very low doses of carbofuran. Accordingly, in the absence of carbofuran data in pup PNS tissues or a surrogate such as RBC data, the Petitioners' evidentiary proffer fails to establish a reasonable possibility that this issue could be resolved in their favor. A hearing is not appropriate in such cases (40 CFR 178.32(b)(2)).

The central tenet of this objection is that regulating based on the effects in the CNS will ensure that the PNS is protected. In this regard, Petitioners do cite to studies in juvenile animals, but all of them are

conducted with chemicals other than carbofuran.[11] Moreover, the Petitioners' evidence fails to demonstrate that the PNS can never be more sensitive than the CNS, or even that the PNS is typically less sensitive than the CNS. Rather, the evidence shows only that the CNS (brain) is sometimes more sensitive, and sometimes less sensitive than the PNS, depending on the chemical involved. Because the data do not show a consistent pattern, it indicates only that the relative sensitivity between the central and peripheral nervous systems varies depending on the chemical involved, which cannot establish that exclusive reliance on brain data as a general proposition will always be protective of PNS effects in pups. Nor can it establish that reliance on the brain data will be protective of the PNS effects in the case of carbofuran.

When data are not available for a specific chemical, conclusions based on other chemicals can only be scientifically supported if it has been demonstrated that the conclusion is always true. If, "in some cases," the conclusion is not true, then in the absence of data on the specific chemical, the conclusion cannot be made for that chemical, and uncertainty exists regarding the effects of the individual chemical. Since there are no data on the effects of carbofuran in PNS tissues or RBC data at low doses in pups, even assuming that they were able to prove that for the specific chemicals identified, the CNS is sometimes more sensitive than the PNS, significant uncertainty would remain

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[11] Most of the studies were conducted on OP chemicals, and expressly caution against extending the results to NMC chemicals such as carbofuran; a point also raised by Petitioners' own experts (Ex 4, 6).

regarding carbofuran's effects on the PNS. This is because the only evidence specific to the effects of carbofuran on the PNS at low dose levels that can be used as a comparison with the brain AChE levels is the adult RBC data.

This also affects the materiality of this objection. If the adult RBC AChE data are not considered, as Petitioners suggest, no carbofuran-specific data exists to demonstrate the level of AChE inhibition in the PNS of either adults or pups at the low dose levels relevant to risk assessment. Thus, even assuming Petitioners could successfully establish every point they raise in this regard, the fact still remains that a decision maker would have no data that provides any information relating to the potential effects of carbofuran on a child's PNS. Given that FFDCA section 408(b)(2)(C) compels the application of a 10X safety factor in the absence of information to account for the presumptive sensitivity of children, the lack of any data bearing on carbofuran's PNS effects would require the Agency to apply a 10X safety factor, rather than the 4X factor applied in the final rule.

A further flaw in the Petitioners' evidence is that it is internally inconsistent. Notwithstanding their allegations (discussed in subissue b below) that RBC data are inherently unreliable and should be discounted in favor of brain data, the carbofuran adult RBC data are one of the primary pieces of evidence proffered to support the claim that reliance on the carbofuran pup brain data will protect against all potential PNS effects (Exhibit 4). As discussed in more detail below, the Report cites to the carbofuran data with adult rats to conclude that brain AChE inhibition correlated closely with RBC AChE inhibition. "This was further

substantiated by the study published by McDaniel *et al.* (Ref. 54), where they report that the 'lowest dose of carbofuran (0.10 mg/kg) significantly decreased brain ChE activity but not RBC ChE or motor activity' * * *" (Id. at 4, 6). Yet having granted scientific validity to the adult RBC data, they must also concede the relevance of the EPA-ORD carbofuran pup RBC data, which clearly demonstrate that at every dose tested, RBC AChE, and therefore the PNS for which it is a surrogate, is more sensitive than the brain in juvenile rats exposed to carbofuran. They raise no challenge specific to the scientific validity of the EPA-ORD data, but rely only on their generic challenge that RBC data are inherently less reliable than brain data. No hearing is warranted based on such evidence. *See* 49 FR 6672 (February 22, 1984) (challenge to one of five related studies; in the absence of any additional data bearing on the clinical study, the objection constitutes nothing more than an allegation); 68 FR 46403 (August 5, 2003) (hearing denied because cited studies only contained equivocal statements supporting objector's position).

Accordingly, the sum of their evidence is no more than mere speculation that the effects of carbofuran exposure in the CNS will be protective of effects in the PNS. This falls far short of the "reliable data" on the safety of infants and children needed to justify the entire removal of the 10X children's safety factor and thus cannot justify a hearing (40 CFR 178.21(b)(2)). *See, e.g.*, 73 FR 42697 (July 23, 2008) (denying hearing where the only evidence submitted was NRDC's claim that if the DDVP two-generation rat reproduction study had been conducted pursuant to the 1998 guidelines it might have shown endocrine effects at lower doses than the doses at which DDVP's

cholinesterase effects were seen on grounds that this was mere speculation); 57 FR 6667 (February 27, 1992) (hearing denied to an objector who challenged FDA's rejection of a study for only containing partial histopathological data on the grounds that "[s]peculation regarding data that do not exist cannot serve as the basis for a hearing").

A detailed examination of Petitioners' evidence follows below.

*(a) Testimony intended to show that brain is the appropriate endpoint.* Petitioners allege that the "critical effect of concern due to carbofuran is nervous system AChE. Brain is a direct measure of such toxic effects, while RBC not linked to any biological function." On this basis, they conclude that brain represents the most appropriate endpoint for risk assessment.

Essentially this testimony fails to prove any dispute of material fact. EPA relied on the carbofuran pup brain AChE inhibition data to establish carbofuran's PoD. The Petitioners have not argued that PNS effects are irrelevant. Indeed, their submissions make clear that effects on the PNS are appropriate considerations in a risk assessment; the only point they dispute is whether brain or RBC data best account for those effects (Exhibits 4, 6).

Alternatively, if they intend to argue that RBC data entirely lacks any scientific validity, this is contradicted in several places by their other objections and their own submissions. As discussed above, the commenters rely on the adult carbofuran RBC data to support their claim that reliance on the pup brain data is adequately protective of PNS effects. Moreover, they explicitly acknowledge that reliance on RBC data

is scientifically valid in the context of the human data (Obj at 13). Consequently, the submitted materials are insufficient to justify the factual determinations urged, and therefore fail to support a determination that an evidentiary hearing is warranted (40 CFR 178.32(b)(2)).

*(b) Testimony purporting to show that reliance on brain data is sufficiently protective of the PNS.* The Petitioners raise several arguments in this regard. First, they allege that, "brain responds rapidly to carbofuran, which readily passes blood/brain barrier" (Obj at 12-13). Petitioners' primary point, however, is that "the extent of brain inhibition by carbofuran more accurately compares with the extent of PNS inhibition, and therefore brain data are adequately protective" (Id.). In support of this claim, Petitioners cite to Exhibits 4 and 6, containing a mixture of "expert testimony" and published studies. None of the information contained in these exhibits is sufficient to establish a reasonable possibility that this issue could be resolved in their favor.

Petitioners' first claim simply reiterates points made in their comments on the proposed rule. As explained in the final rule, EPA agrees that the data show that the brain responds rapidly to carbofuran, and that it readily passes the blood/brain barrier. However, evidence regarding the speed with which the brain reacts proves nothing with regard to the relative sensitivity of PNS tissues (Ref. 85 at 46). Petitioners have presented nothing that challenges the substance of EPA's response. Consequently, these claims do not present a live controversy as to a material issue of disputed fact; both parties agree on the facts at issue, which is that the brain responds rapidly to carbofuran.

Moreover, a simple repetition of comments made on the proposal without more is insufficient to warrant a hearing. *See, e.g.*, 73 FR at 42698-42699 (July 23, 2008) (denying several NRDC hearing requests because the objections were based on EPA's preliminary DDVP risk assessment, rather than the revised risk assessment published with the final order); 53 FR 53176 (December 30, 1988) (where FDA responds to a comment in final rule, repetition of comment in objections does not present a live controversy unless objector proffers some evidence calling FDA's conclusion into question); 62 FR 64102, 64105 (December 3, 1997) (objector claimed that addition of ethoxyquin invalidated studies; hearing denied because objector did "not dispute FDA's explanation in the final rule as to why addition of ethoxyquin did not compromise the CIVO studies, and provided no information that would have altered the agency's conclusion on this issue").

Petitioners' second point—that brain AChE inhibition correlates closely with PNS inhibition, and demonstrates that reliance on brain data will be protective of the PNS—is a disputed material issue of fact that could warrant a hearing, except that none of the evidence submitted in support of this point presents a reasonable possibility that the Petitioners could establish the points alleged. Consequently, they have failed to demonstrate that a hearing is warranted on this objection (40 CFR 178.32(b)(2)).

(*c*) *Exhibit 4*. This exhibit consists of a report by Kendall Wallace, PhD, entitled "Expert Report: Carbofuran FQPA Safety Factor," along with published studies (Ref. 17, 51, 53, 54, 59, 61, 62, 72). The report argues that, "it is my opinion that for

carbofuran, the evidence indicates that inhibition of brain AChE is an appropriate surrogate for PNS AChE inhibition and that there is reasonable certainty that a PoD for carbofuran based on brain AChE inhibition is protective of any adverse CNS and PNS effects." The only carbofuran evidence directly cited in support of this allegation is data conducted on adult animals, using RBC AChE data, which they elsewhere try to discount. This assumes that adults and pups are similarly sensitive despite the carbofuran-specific evidence to the contrary. No evidence is discussed or submitted to support this assumption. This therefore constitutes a mere allegation, which does not justify a hearing.

None of the published studies conducted with other chemicals cited in the Report provide more than equivocal support for the points above; in fact, in several instances, the study results support EPA rather than the Petitioners.[12] The studies contained in this exhibit fall into two general categories. The first group of studies consists of a subset of the chlorpyrifos literature—which is generally more relevant to the subissue discussed in the next objection, arguing that RBC data are not a good surrogate for the PNS—rather than demonstrating affirmatively that brain is a protective surrogate for the PNS. The second category of studies is one paper on physostigmine, a carbamate,

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[12] It is interesting to note that, in Exhibit 4, the expert actually faults EPA for comparing OP and NMC pesticides, saying "Although OP pesticides inhibit AChE, they are completely different from carbofuran and other N-methylcarbamates * * *." (Exhibit 4 at 4). Yet the Exhibit includes papers on effects of chlorpyrifos, an OP, and these papers are not discussed in the text of the Exhibit.

that is discussed in the body of the report. All but one of these studies was conducted using adult rats.

Marable, *et al.* (Ref. 51) and Nostrandt *et al.* (Ref. 59) are two of the chlorpyrifos studies Petitioners submitted as part of the comments on the proposed rule, and they contain little evidence to demonstrate that brain data correlate well with the PNS, and thus are generally protective of the PNS. Marable *et al.* involved chronic exposures to adult dogs; in addition to the fact that adult animals were used, and therefore provide evidence of little relevance to the question at issue, there are significant differences between the results of chronic and acute exposures. As a result of the repeated exposures, blood, brain and peripheral tissues were at steady state, which cannot occur from an acute exposure, and therefore this study can provide no information on the effects from acute exposures. Nostrandt *et al.* actually reported that, following a single low dose of chlorpyrifos, brain inhibition was less (not greater) than the inhibition obtained in heart which is part of the PNS (although higher inhibition was not seen in the diaphragm or retina, other parts of the PNS). At higher doses, the inhibition in brain and peripheral tissues were more similar. Thus, this study contradicts the Petitioners' claim that brain data will be protective of all PNS effects. Petitioners offer no explanation of how the resubmission of these studies addressed EPA's conclusion in the final rule that the chlorpyrifos data failed to prove their claim.

Chen, *et al.* (Ref. 17), another study of chlorpyrifos, discussed whether plasma or RBC AChE should be used to establish a regulatory endpoint in humans and compared data from several animal studies, some of which were conducted with adults and some with pups.

This is the only study in Exhibit 4 that contains data on pups. The results of one of the studies reported in Chen, *et al.* shows that at the lowest doses, inhibition was greater in the heart, which is part of the PNS, than in the brain (56% and 41% respectively); note that these are the data in adult rats reported in Nostrandt et al. (described above). Based on data from a developmental study of chlorpyrifos by Hoberman (Ref. 37), Chen *et al.* reported that the doses estimated to produce 50% inhibition in heart and brain actually show that in 5-day old pups (both males and females), the heart is 2-3 times more sensitive than brain. Thus, this study contradicts Petitioners' claim that brain data will be protective of PNS effects, since the PNS inhibition was greater than brain at the lowest doses in both adults and pups. And in fact, it supports EPA's concern that the absence of data at low doses is significant because the effects at low doses can differ significantly from those at higher doses. The data from Hoberman showed that at higher doses, ranging from 30-100 mg/kg, the levels of inhibition in the brain were higher than the levels in the PNS (Ref. 37 at 16)—the exact opposite of what occurred at the lowest doses.

The second group of studies consists of data on NMC chemicals. McDaniel *et al.* (Ref. 53) and Padilla *et al.* (Ref. 62) were cited in support of the claim that the difference in sensitivity between the brain and RBC is generally less for NMC chemicals. These studies were conducted with adult animals, and so do nothing to address the question before the Agency with respect to pups. These studies merely confirm the existing carbofuran data in adults, which shows that at the lowest dose tested, brain and RBC are essentially the same.

Somani *et al.* (Ref. 72) is a study on another NMC chemical, physostigmine, in adult animals, cited to support the claim that "in adult rats, brain AChE is somewhat more sensitive than RBC or peripheral AChE to inhibition by acute doses of physostigmine." As an initial matter, it is unclear that this study provides more than equivocal support for their claim; the study authors claim only that the brain "appears" to have the lowest values. However, even conceding that this study shows that the CNS tissues in adult rats are more sensitive to the effects of physostigmine than the PNS tissues, the data in this study is of limited relevance to the issue at hand, which is the effects in juveniles. Thus it is ultimately insufficient to affirmatively support the Petitioners' claim.

In sum, based on the evidence contained in this exhibit, EPA concludes that there is not a reasonable probability that the proffered evidence would resolve the issue in Petitioners' favor, and that consequently no hearing is warranted on this basis. First, all but one of the studies discussed in this exhibit were conducted with adult animals, rather than pups. As such, they provide evidence of little relevance to the question of whether pups' PNS are more sensitive than the CNS. In the absence of carbofuran PNS data, or pup RBC data, much of this evidence is effectively mere speculation about whether adult data will be predictive of pup responses, which cannot justify a hearing (40 CFR 178.32(b)(1)).

*(d) Exhibit 6.* This exhibit consists of a report by Lucio Costa, PhD,. entitled, "Expert Report: Carbofuran's FQPA Safety Factor and Interspecies Uncertainty Factor," as well as published literature studies conducted with chlorpyrifos and disulfoton,

both OP pesticides, and a single study with propoxur, an NMC pesticide (Refs. 71, 19, 20, 21, 61, 52, 41, 64, 16). According to Costa, these studies generally show that there was similar or greater AChE inhibition in brain than in the PNS tissues of heart, ileum, or the diaphragm, which Petitioners claim proves that reliance on carbofuran pup brain AChE inhibition data will necessarily be protective of all effects in the PNS (Exhibit 6 at 3). The exhibit also references a human incident study (Ref. 50) of carbamate poisoning in early childhood and in adults, claiming that, "Lifshitz * * * showed that signs of adverse effects in the CNS, rather than PNS, prevailed in young children at the low dose levels covered by the paper."

EPA concludes that there is not a reasonable probability that the evidence contained in this exhibit would resolve the issue in Petitioners' favor. The results of these studies fail to demonstrate the point for which Petitioners cite them—that brain AChE is always equally or more sensitive than PNS AChE, and therefore exclusive reliance on brain data can be assumed to be protective. Consequently, the fact that Petitioners can identify examples of other chemicals, whether OPs or NMCs, that sometimes affect the brain more severely than the PNS does not prove that this will be the case with carbofuran. Furthermore, in several of the cited examples the Petitioners misinterpret the findings, which actually support EPA's position.

As explained in EPA's final rule, Petitioners are relying on only a subset of the chlorpyrifos data. The data, when examined in total, do not support a conclusion that brain data will always be protective of PNS effects (74 FR 23054-23055 (May 15, 2009)). But

even relying solely on the studies Petitioners reference in this exhibit, it is clear that brain is not always inhibited to the same degree as peripheral tissues, nor is it always protective of peripheral tissues. The data in Padilla *et al.* (Ref. 61) are the only chlorpyrifos data that support a conclusion that reliance on the CNS data will be protective of the PNS. However, the Padilla study involved chronic dosing of rats via the feed, and as such, cholinesterase measurements reflected steady-state conditions. This study cannot provide information relevant to acute exposure. None of the other chlorpyrifos studies referenced in this exhibit support this conclusion. In Mattson *et al.* (Ref. 52), and Hunter *et al.* (Ref. 41), following a single dose to pregnant dams, heart and liver tissues were more inhibited than brain tissues. Similarly, in Richardson and Chambers (Ref. 64), where repeated doses were administered to pregnant dams, at both the low and high doses, the lung tissue was more inhibited than the brain tissue in the one-day old pups. In Carr *et al.* (Ref. 16), the results were more equivocal; in a repeated dosing study using pups of varying ages, whether brain or peripheral tissues were most inhibited depended on the age of the pups and the dose. Nevertheless, Carr (2001) showed that brain inhibition decreased as the age of the pups increased, even though inhibition in the heart tissues did not. In other words, the submitted material only supports a conclusion that brain is sometimes inhibited by chlorpyrifos to the same degree as the peripheral tissues, and in reality, the studies show that brain is often inhibited to a lesser extent than peripheral tissues. This cannot support a conclusion that reliance exclusively on brain data will necessarily be protective

in the absence of some additional carbofuran-specific evidence.

The results are similar for the disulfoton studies. Schwab *et al.* (Ref. 71) shows that after both a single dose and repeated doses, the brain and peripheral tissues were equally inhibited. However, these results are contradicted by Costa *et al.* (Ref. 19) and Costa and Murphy (1983), where the results varied depending on the dosing and the brain area examined. In Costa and Murphy (Ref. 21), diaphragm tissues were more inhibited than brain tissues after a single dose of disulfoton, while after repeated doses, brain and diaphragm tissues were similarly inhibited. Thus, the relative sensitivity between CNS and PNS changes with repeated dosing, and these studies provide no information on RBC inhibition with which to compare the other tissues.

Finally, the Lifshitz study does not support the claim for which it was cited. The study presents no data on the dose levels associated with the poisoning incidents, and in fact concludes that there was "insufficient information to compare the doses ingested by [adults and children]." However, based on the symptomology reported (comas, stupor, and severe hypotoxicity) it is likely that the doses were high, not low, as the Report claims. Also, this study cannot be used to discount PNS effects in children; a large percentage of the children clearly showed PNS effects (myosis, diarrhea). In addition, because this was a retrospective study of patients admitted to a hospital intensive care unit, given the severity of some of the CNS symptoms, such as comas, it is not unlikely that even if the subjects also showed PNS symptoms, they were not reported. Finally, the study authors'

conclusion was that in children, the "clinical presentation [of carbamate poisoning] differs from adult poisoning manifestations" (Ref. 50). Or in other words, that the effects in adults from exposure to carbamates such as carbofuran are not necessarily predictive of the effects in children. It is difficult to see how this study could be fairly argued to support Petitioners' allegations.

In conclusion, the totality of the evidence in Exhibits 4 and 6 fail to support Petitioners' contention. As shown in Table 1 below, the majority of the study results demonstrate that the PNS is frequently more sensitive than the CNS. The remainder, taken in the light most favorable to the Petitioners, provide merely equivocal support.

[Table 1 omitted]

Accordingly, Petitioners' proffer is facially insufficient because there is no reasonable possibility that it can establish a necessary element of Petitioners' objection—that there are "reliable data" that show it would be safe for infants and children to remove entirely the 10X children's safety factor.

*iii. Denial of objection.* The objections do not address the fundamental issue that EPA is required by the statute to resolve: Are there 'reliable' data to support reduction or removal of the statutory 10X for protection of infants and children? The statute compels that EPA may only revise the 10X default safety factor if, "on the basis of reliable data" EPA can conclude that the alternative safety factor will be "safe" (21 U.S.C. 346a(b)(2)(C)). The statute also requires EPA to account for the "completeness of the toxicity data" in making this determination (Id). In this case, the Agency concluded that there are sufficient data to

reduce the 10X safety factor but there is insufficient information to justify removing the factor entirely.

Similar to other AChE inhibiting pesticides, carbofuran can affect both the central and peripheral nervous system. Because the relative sensitivity of the central and peripheral nervous system varies among pesticides and the children's safety factor should account for the most sensitive toxicity endpoint, the Agency considers the availability of data in both the central and peripheral nervous systems important in its safety factor evaluation.

As shown in Figure 1, above, there are several datasets that evaluate the effects of carbofuran on the central nervous system (*e.g.*, brain AChE inhibition) in juvenile rats. There are no AChE data from peripheral tissues. Lack of peripheral AChE data is typical of NMCs due to the rapid reactivation of AChE. As a matter of science policy, the Agency typically uses AChE data from blood, particularly RBCs, as a surrogate measure for the peripheral nervous system (Refs. 76, 87). In the case of carbofuran, RBC AChE data from two separate studies submitted by FMC are considered unreliable and unusable in human health risk assessment (Ref. 83). Data from EPA's ORD includes high quality RBC AChE data, but only high doses were used in the ORD studies. Data at the low end of the dose response curve are not available for assessing the effects in juvenile rats, which are the doses relevant for human health risk assessment. Thus, because reliable data are available to assess affects on the CNS and some surrogate data are available to assess the PNS, the Agency believes that the children's safety factor can be reduced. However, this factor cannot be completely removed since the

available carbofuran data show that RBC AChE inhibition in pups is more sensitive than brain AChE inhibition.

Given that (1) data from other AChE inhibiting pesticides show that direct measures of peripheral nervous system (*e.g.*, lung, heart, and liver AChE) can be more sensitive than brain AChE inhibition; (2) a surrogate measure of the peripheral nervous system (RBC AChE) is more sensitive in juvenile rats to carbofuran; and (3) clinical signs consistent with toxicity to the peripheral nervous system were seen at very low doses, the Agency can not be confident that assessing risk using brain AChE inhibition is protective of potential effects in the peripheral nervous system for infants and children. For example, in the first FMC-sponsored comparative ChE studies (Ref. 4) every pup at the 0.3 mg/kg dose group exhibited tremors. The range-finding portion of the second FMC-sponsored comparative ChE study (Ref. 1) resulted in tremors in rats exposed to 0.3 mg/kg carbofuran (2/5 males and 2/5 females) within 15 minutes post-dosing.

Additional evidence for sensitivity of the PNS comes from carbofuran data in pregnant rats that showed clinical signs that may be indicative of peripheral toxicity. The California Department of Pesticide Regulation (CDPR) has calculated a $BMD_{10}$ and $BMDL_{10}$ of 0.04 and 0.03 mg/kg/day, respectively, for mouth smacking and chewing in pregnant rats exposed to carbofuran. These signs are early indicators of toxicity from some cholinesterase inhibitors (Ref. 56). This is notable for two reasons. First, cholinergic toxicity (*e.g.*, tremors, miosis, salivation) may be observed following inhibition of

blood, but not brain, cholinesterase. This was the case with fenamiphos (an OP pesticide), even up to maximally tolerated doses (Ref. 53). Second, the $BMDL_{10}$ from the mouth smacking and chewing in pregnant rats is similar to that being used by EPA for brain AChE in juveniles. The similarity of the CDPR BMD in adults and EPA's BMD in juveniles is striking because all of the available data show that pups are more sensitive than adults to carbofuran toxicity. This therefore suggests that behavioral effects and/or clinical signs may be occurring in juvenile animals at lower doses, but which cannot be detected, in part due to the challenges with assessing clinical signs in juvenile rats. As noted by the SAP, this "limitation reflects the limited range of toxic signs detectable in very young pups (p. 54)." This provides further support that the lack of pup data at lower doses is significant, because the Agency cannot fully evaluate the behavioral effects on juvenile animals.

Further support for the Agency's concern comes from other clinical reports of the effects of carbamate poisoning in children. For example, Lifshitz reported that all children presented with CNS symptoms (coma, stupor), but CNS symptoms were observed in only 54% and 23% of children as reported by Zweiner and Ginsburg (1988) and El-Naggar *et al.* 2009 (Refs. 91, 26). Peripheral muscarinic symptoms were the most commonly reported (73% and 100%) signs of toxicity in these latter two reports. These markedly different findings emphasize that conclusions cannot be unequivocally drawn from only one study.

In addition, Petitioners' own data show that effects can differ significantly between high and low doses. In Chen, for example, the data from Hoberman showed

that at the lowest doses the levels of inhibition were higher in the PNS than in the brain, but at higher doses, the levels were higher in the brain.

Thus, for a number of reasons, the Agency has concerns that children's PNS may be more sensitive to the effects of carbofuran than the CNS. This concern is the basis for retention of a portion of the children's safety factor.

The carbofuran RBC data in adult animals does not resolve this question. There can be substantial differences in response between pups and adults, and, as noted, the data show clearly that pups are more sensitive to the effects of carbofuran. It is not unusual for juvenile rats, or indeed, for infants or young children, to be more sensitive to chemical exposures as metabolic detoxification processes in the young are still developing. Because pups are more sensitive than adult rats, data from pups provide the most relevant information for evaluating risk to infants and young children and are thus used to derive the PoD. In addition, typically (and this is the case for carbofuran) young children (ages 0-5) tend to be the most exposed age groups because they tend to eat larger amounts of food per their body weight than do teenagers or adults.

*b. Objection/hearing request subissue: Reliance on RBC AChE inhibition data as a surrogate for PNS effects.* This objection also challenges EPA's decision to retain some portion of the presumptive 10X children's safety factor, rather than remove it entirely. As explained above, EPA retained a portion of the presumptive 10X children's safety factor because of the absence of sufficient data on PNS effects in juveniles and the uncertainty created by the limited data relevant to the PNS that showed greater sensitivity in

juveniles. In the previous subissue, Petitioners argued that in fact there is no uncertainty created by the lack of low dose RBC data and the finding of sensitivity in the RBC AChE data because brain AChE data is protective of PNS effects. In this subissue, Petitioners attempt to buttress their first argument by claiming that RBC AChE data are not an "appropriate surrogate" for PNS effects, and should not have formed the basis for retention of any portion of the children's safety factor.

Petitioners do not argue that RBC data are entirely irrelevant, but rather that brain data are "preferred." They raise several points in support of this contention; first, that "RBC AChE inhibition data are only preferred for risk assessment purposes in two circumstances: (1) Where the PoD is set using data from human studies where only RBC data are available or (2) where data from the relevant target tissues are unavailable." They allege that, despite the absence of carbofuran data in the PNS tissues, brain is preferred in this case because the brain is "target tissue" from the nervous system, and because brain data are a "better predictor" of PNS effects than RBC. As further evidentiary support, they cite to evidence from OP studies that RBC AChE can "in some cases" be inhibited to a greater degree than either PNS or brain AChE, and therefore reliance on RBC AChE data can overstate potential PNS effects. They also argue that RBC AChE is more variable and less reliably measured at low response levels, such as 10% AChE inhibition. The evidence in Exhibits 4 and 6 is also proffered in support of this objection.

*i. Background.* EPA's well-established policy when evaluating cholinesterase-inhibiting compounds

is to rely on data in the target tissue where it is available (Ref. 76). As noted in the preceding section, measures of AChE inhibition in the PNS are rarely collected for NMC pesticides. And in fact, there are no carbofuran data measuring effects in PNS tissues. But in the absence of target tissue data, as a matter of science policy, EPA typically uses RBC AChE inhibition data as an indicator of possible effects on AChE in the PNS for number of reasons. (Ref. 76 at 32). Although RBC AChE inhibition is not adverse in itself, it is a surrogate for inhibition in peripheral tissues. As such, RBC AChE inhibition provides an indirect indication of adverse effects on the nervous system (Id.).

Petitioners raised many of the same issues raised in the objections in their comments on the proposed rule. For example, they argued that, "as a matter of science policy, brain AChE inhibition is the preferred endpoint over RBC AChE inhibition." They also argued that no physiological function has been demonstrated for RBC, and RBC AChE inhibition is not itself an adverse effect.

In the final rule, EPA responded to each of their comments, but concluded that no information had been submitted to justify altering the Agency's general policy that reliance on RBC is appropriate as a surrogate for PNS effects in the absence of direct measurements in PNS tissues.

*ii. Denial of hearing request.* This subissue does not raise a dispute of material fact. There is no dispute regarding many of the facts raised in this objection: When data in the target tissue are available, it is preferred over a surrogate. RBC AChE can be more variable and less reliably measured at low response

levels than brain AChE. RBC AChE inhibition can, in some cases, be more extensive than PNS AChE inhibition. Equally, there is no dispute that no physiological function has been demonstrated for RBC, and RBC AChE inhibition is not itself an adverse effect. All of these points are explicitly recognized in EPA's Cholinesterase policy and in the tolerance revocation rulemaking record, and relate purely to the ease or wisdom of relying on these measures rather than others, as opposed to the scientific invalidity of such data. The only point on which there is a dispute is, given that there is no data in the target tissues of the PNS, which data—brain or RBC—is "preferred." The Petitioners expressly acknowledge this to be the issue: "There are other surrogate measures of PNS AChE that could have been selected by OPP, such as brain AChE" (Exhibit 4 at 5). This is clearly a question of scientific policy, since both EPA and the Petitioners agree on the scientific validity and relevance of RBC AChE inhibition data. As they expressly acknowledged in their comments, the choice of which surrogate to use is a matter of "science policy" (Ref. 18). Indeed, Petitioners explicitly concede the propriety of relying on RBC data "where data from the relevant target tissues are unavailable, or when relying on human data, where RBC AChE inhibition data are the only data available (Obj at 13). Hearings are not appropriate for debating questions of policy (40 CFR 178.32(b)(1)).

Nor does the proffered evidence present any other issue that would warrant a hearing. The evidence submitted in Exhibits 4 and 6 on this point only relates to the question of whether brain data can sometimes correspond more closely with PNS effects than RBC

AChE data, rather than the question of whether the RBC data are scientifically invalid. Or in other words, the submitted materials relate only to the point that reliance on RBC data is unnecessarily conservative, because sometimes it overestimates the potential PNS effects, rather than to the factual question of whether RBC data bears no relation whatsoever to PNS effects. Unless Petitioners can show that RBC AChE is not related to CNS effects generally or specifically for carbofuran, or that brain AChE is protective of CNS effects generally or specifically for carbofuran, then the mere fact that RBC AChE may be a conservative, or even very conservative, indicator of PNS effects is simply immaterial to the question of whether there are "reliable data" to justify removing the presumptive 10X children's safety factor in the absence of sufficient RBC AChE data. As shown in the discussion of subissue 1, the Petitioners' evidence does not demonstrate that reliance on juvenile brain data as a surrogate for effects in the juvenile PNS will guarantee that the levels chosen on that basis will be predictive of all PNS effects from carbofuran, because the PNS effects occur only at the same or higher doses than those that produce effects on the brain AChE—*i.e.*, that the brain data "bound" all potential PNS effects. Nor, as discussed below, does any of Petitioners' evidence support a conclusion that RBC AChE is unrelated to PNS effects.

Indeed, much of the evidence in the Exhibit 4 and 6 Reports is ultimately an irrelevance, and thus fails to present a material factual dispute. Instead of focusing the stated objection—RBC AChE is inappropriate marker for CNS effects—the Reports attempt to link EPA's children's safety factor decision to findings

concerning chlorpyrifos (Exhibit 4 at 4). In fact, a fair portion of the Report in Exhibit 6 is dedicated to a rebuttal of EPA's conclusion that the majority of the more recent and more relevant chlorpyrifos evidence did not support Petitioners' contention. EPA, however, has been clear throughout the rulemaking that the basis for retention of a children's safety factor has been the absence of carbofuran data to determine the levels of exposure that will be protective of children's PNS, in the context of a statutory provision that expressly requires EPA to account for missing data. EPA's point in discussing the chlorpyrifos data—which Petitioners initially raised as relevant—was simply that it showed that because peripheral tissues can be more sensitive than central nervous system tissues, the absence of data addressing carbofuran's effects on the PNS is highly relevant. Whatever the chlorpyrifos data show cannot resolve the extent of carbofuran's risks. As the Petitioners' experts themselves point out, "Even conceding that [EPA's conclusion in the final rule that peripheral tissues are often shown to be more sensitive than brain tissue following exposure to chlorpyrifos] may be true, it is still unclear how this would be relevant to carbofuran * * *" (Exhibit 6 at 3). Accordingly, this evidentiary submission fails to demonstrate that a dispute exists on a question of material fact.

Finally, their submission provides an inadequate basis on which to grant a hearing; because evidence is not proffered on critical points, the objection ultimately rests on allegation, speculation, and general denials (40 CFR 178.32(b)(2)). As discussed in preceding section, the majority of the evidence comes from adult data, which are of limited relevance. Further, and

more significantly, the evidence fails to demonstrate that brain data always—or even more frequently than not—correlates more closely with PNS effects than RBC AChE data. Instead, the proffered evidence only demonstrates that whether brain or RBC data correlate better with actual PNS effects can vary depending on the chemical. This, therefore, cannot resolve the question as to whether, in the case of carbofuran, brain AChE data will necessarily correspond more closely with the PNS. Finally, as also discussed in the preceding section, Petitioners' argument is internally inconsistent, because they rely on carbofuran adult RBC AChE data to support their argument that exclusive reliance on the brain data will be protective of potential PNS effects in pups. No hearing is appropriate where the proffered evidence fails to prove the points for which it is offered, or offers merely equivocal support (See, 73 FR 42705 (July 23, 2008) (hearing denied because published articles focus on an issue not applicable to the facts of the case at hand); 68 FR 46405-46406 (August 5, 2003) (a hearing was denied because the cited studies only contained equivocal statements)).

A detailed examination of Petitioners' evidence follows below:

*(a) Exhibit 4.* As discussed in the previous objection, this exhibit consists of a report, along with published studies. The Report criticizes EPA for assuming that RBC AChE inhibition provides "a stronger and more quantitative concordance with the sensitivity of AChE of the PNS to inhibition by carbofuran," on the ground that EPA failed to cite to evidence to support this inference (Exhibit 4 at 5). In the absence of such evidence, the report concludes that,

"one cannot discount the plausibility that brain AChE may be a more quantitative and representative surrogate measure of PNS sensitivity" (Id). To support this allegation, the report argues that the cited NMC data show that the difference in sensitivity between brain and RBC shown with NMC chemicals is less than the differences seen with OP chemicals, citing studies by Padilla *et al.* (Ref. 62) and McDaniel *et al.* (Ref. 54). In this regard, the Report actually misquotes McDaniel *et al.* The Report claims that the paper concluded that there was a stronger correlation between brain AChE inhibition and motor activity. The study actually concluded that there was little difference between brain AChE inhibition and RBC AChE inhibitions ("higher correlation for brain and motor activity compared to RBC were not significantly different.") (Ref. 54). In any event, the Report's equivocal conclusion that "one cannot discount the plausibility" that brain AChE might be the most representative measure of PNS effect is, on its face, insufficient grounds to overcome the statutory presumption for retention of the additional 10X children's safety factor in the face of the evidence of children's additional sensitivity to carbofuran, and the lack of carbofuran data in PNS tissues or in a surrogate for such tissues, RBC AChE.

Chen *et al.* (Ref. 17), which was discussed at length in the earlier objection, evaluated whether plasma or RBC AChE should be used to establish a regulatory endpoint; it did not evaluate whether brain AChE would be an appropriate surrogate for PNS effects. It is true that the authors conclude that "[i]nhibition of RBC AChE activity is consistently exhibited at lower dosages of chlorpyrifos than those required to result in

clinical symptoms of OP toxicity, or alterations in cognitive functional responses." However, since the study authors ultimately concluded that, "inhibition of RBC AChE activity is an appropriate surrogate for measurement of chlorpyrifos exposure and provides a conservative endpoint for establishing appropriate margins of safety for both adults and infants," it is difficult to see how this could be argued to provide unequivocal support for Petitioners' objections.

*Exhibit 6.* This exhibit consists of a report by Lucio Costa, PhD, entitled, "Expert Report: Carbofuran's FQPA Safety Factor and Interspecies Uncertainty Factor," as well as published literature studies. The report discussed the results of several published studies that they claim demonstrate that "where available, brain AChE inhibition data provide a superior surrogate" to RBC data because "in some cases RBC AChE may overestimate PNS AChE inhibition, while in other cases * * * RBC AChE inhibition may underestimate actual AChE inhibition in the PNS." In support of this allegation, the report references data from several studies conducted with chlorpyrifos and disulfoton, both OP pesticides, and a single study with propoxur, an NMC pesticide (Refs. 16, 19, 20, 21, 41, 52, 61, 64, and 71). According to the Report, these studies generally show that there was similar or greater AChE inhibition in brain than in the PNS tissues of heart, ileum, or the diaphragm, which Petitioners claim proves that reliance on carbofuran pup brain AChE inhibition data is more predictive of all effects in the PNS. The exhibit also references a human incident study (Ref. 50) of carbamate poisoning in early childhood and in adults, claiming that, "Lifshitz * * * showed that signs of

adverse effects in the CNS, rather than PNS, prevailed in young children at the low dose levels covered by the paper."

In its denial of the hearing request on the previous issue, EPA examined the results of the studies in this exhibit at length, and demonstrated that the results of the studies failed to support a conclusion that brain data correlate more closely to PNS effects than RBC data. Indeed, in most of these studies, brain AChE inhibition poorly reflected the AChE inhibition in PNS tissues. For example, the Carr *et al.* study results, reproduced in Table 1 of Exhibit 6, showed that for PND 10, 16, and 20 rat pups, the heart tissue had the greatest levels of inhibition, and that PND 16 and 20 rat pups had greater levels of inhibition in lung tissue than in the brain (Ref. 16 at 3). Further, since the study was conducted with serum, which contains no RBC, it is unclear how this study could prove that brain data are a better indicator of PNS effects than RBC data.

The remainder of the report consists of criticisms of EPA's conclusions, and contentions that EPA was inconsistent, without citation to biological evidence to support these claims. For example, the Report addresses EPA's rejection of the Bretaud study in goldfish on the grounds that the "distribution of carbofuran across fish and mammalian tissues may be quite different," by criticizing EPA for failing to provide "evidence or a citation to support this point" (Exhibit 6 at 1). But they cite to nothing demonstrating the similarity of fish and mammalian tissues or otherwise supporting their proposed extrapolation across taxa; at this stage of the administrative process the obligation is on the

Petitioners to come forward with evidence to call EPA's conclusions into question. *See*, 73 FR 42683, 42706, July 23, 2008 ("NRDC does no more than state 'we are aware of no statistical test' which would support EPA's use of the Gledhill data. As EPA's regulations make clear, a mere 'denial' of an EPA position is not enough to satisfy the standard for granting a hearing."); 53 FR 53176, 53199, December 10, 1982 ("Rather than presenting evidence, [the objector] asserts that FDA did not adequately justify its conclusions. Such an assertion will not justify a hearing."). The report also attempts to dismiss EPA's conclusions by complaining that EPA's assessment fails to include "any analysis of the relationship between RBC AChE and PNS AChE." This also, cannot justify a hearing. As has been previously noted, FMC, who bears the statutory burden for producing such data, has failed to provide data in the PNS that would allow EPA to make the suggested comparison (*See*, 73 FR 42683, 42699, July 23, 2008 (hearing denied where NRDC made no evidentiary proffer supporting its claim that each of the factors cited in EPA's risk assessment "poses a serious risk of understating the risks"); 70 FR 21619, April 27, 2005 (objector questioned exposure assessment and studies relied on for assessment; hearing denied because no information presented); 72 FR 39557, 39560, July 19, 2007 ("Although Public Citizen alleged that the studies that FDA evaluated do not support the safety of x-rays of 10 MeV or lower used for inspection of cargo containers that may contain food, Public Citizen did not present any evidence that would have led to a different conclusion concerning the safety of the subject additive.").

*iii. Denial of Objection.* EPA's well-established policy when evaluating blood cholinesterase inhibition is to use RBC AChE data as an indicator of possible effects on AChE in the PNS; EPA adopted this policy for a number of reasons (Ref. 76 at 32). EPA's reasoning here is straightforward. As a biomarker of exposure, blood AChE inhibition can be correlated with the extent of exposure. There is often a direct relationship between a greater magnitude of exposure and an increase in incidence and severity of clinical signs and symptoms as well as blood AChE inhibition. In other words, the greater the exposure, the greater the amount of AChE inhibition that will be present in the blood and the greater the potential for an adverse effect to occur. RBC measures of AChE inhibition also provide: (1) Pharmacokinetic evidence of absorption of the pesticide and/or its active metabolite(s) into the bloodstream and systemic circulation; and (2) pharmacodynamic evidence of binding to AChE, the neural form of the target enzyme. Because the interaction with AChE is widely accepted as a key event of the mechanism of toxicity for anticholinesterase pesticides, inhibition of this AChE in the blood creates the presumption that a chemical also is causing inhibition of neural AChE. Chemicals are absorbed into the blood and transported to the PNS. Pharmacokinetically, the blood compartment and the PNS are "outside of" the central nervous system, *i.e.*, separated from the CNS by the blood-brain barrier. Thus, RBC measures of AChE activity are viewed as a better surrogate for the effects on AChE in the peripheral nervous system than are enzyme changes in the CNS. Because data on AChE inhibition in the PNS have rarely been gathered in animals, blood AChE inhibition measures are generally the only information

available to assess the potential of chemicals to inhibit AChE in the peripheral nervous system.

Finally, based on the record, FMC seemingly intended in the past for RBC AChE to be used as a surrogate for peripheral AChE inhibition. In 2005, FMC submitted a time course study with plasma and RBC AChE inhibition following acute exposure to carbofuran in adult rats. The title of this study is "The toxicokinetics of peripheral cholinesterase inhibition from orally administered carbofuran in adult male and female CD rats (Ref. 5)." Although this study is entitled "peripheral cholinesterase inhibition," there are no actual measures of peripheral toxicity (*e.g.*, liver, lung, heart). Instead, RBC and plasma ChEs are the only measures included. That report states that "carbofuran reversibly inhibits cholinesterase activity by binding to acetycholinesterase in red blood cells * * * Carbamylation of cholinesterase after the association of carbofuran leads to an accumulation of acetylcholine and inhibition of nerve function at the neuronal and neuromuscular synapse." Based on this statement, FMC assumed at the time of conducting and submitting this study that measures of RBC AChE were relevant for predicting neurotoxicity and for use in risk assessment. For all of these reasons, the Petitioners' objection is denied.

*c. Objection/hearing request subissue: "Lip-smacking" as CNS effect.* Petitioners object that EPA's evidence of "lip smacking" in a carbofuran adult developmental rat study does not support concern for potential PNS effects because lip smacking is more properly correlated to CNS, rather than PNS inhibition. In support, the Petitioners proffer testimony that relies on four published studies, none of

which was conducted with carbofuran. The papers describe pharmacological and physiological analyses of the bases of "purposeless chewing movements", "chewing jaw movements", "chewing motions and tongue protrusions", and "tongue protrusion and gaping" seen in rats dosed with either cholinergic or dopaminergic drugs.

*i. Background.* In the proposed rule, in addition to the data in pups showing frank PNS effects (tremors), EPA discussed the results of another carbofuran study that appeared to be a possible consequence of PNS inhibition, to provide further explanation of the basis for EPA's concern that carbofuran could cause adverse PNS effects. The proposed rule stated that "[t]here is indication in a toxicity study where pregnant rats were exposed to carbofuran that effects on the PNS are of concern; specifically, chewing motions or mouth smacking was observed in a clear dose-response pattern immediately following dosing each day" (73 FR 44873, July 31, 2008). EPA explained that the California Department of Pesticide Regulation calculated a $BMD_{05}$ and $BMDL_{05}$ of 0.02 and 0.01 mg/kg/day, and established the acute PoD based on this study. The Agency also explained that "[t]hese BMD estimates are notable as they are close to the values EPA has calculated for brain AChE inhibition and being used as the PoD for extrapolating risk to children" (73 FR 44873, July 31, 2008). The similarities of the BMDs in adult and juvenile rats suggests that toxicity may be occurring in juvenile animals which cannot be detected due to the challenges with assessing clinical signs in juvenile rats.

The Petitioners did not raise the allegation contained in their objections as part of the Petitioners'

comments. The context in which "lip smacking" was addressed was a sentence that states, "One issue raised at the FIFRA SAP meeting was whether 'lip smacking' observed in the adult females in the developmental toxicity study were the result of PNS or CNS AChE inhibition" (Ref. 18 at 82). In a footnote to this allegation, the Petitioners stated "Moreover, it is impossible to tell from the study data whether this "lip smacking" was a PNS or a CNS effect." (Ref. 18 at 82). The Petitioners' comments focused instead on the contention that the study was irrelevant because the dose levels in the study were higher than the dose levels at which EPA was regulating for AChE inhibition (Ref. 18 at 82).

EPA did not respond to the Petitioners' description of the discussion at the SAP, since it correctly characterized the discussion. However EPA responded fully to the Petitioners' comment regarding the dose levels in the final rule and response to comments.

*ii. Denial of hearing request.* There can be no legitimate argument that this comment raised the issue in sufficient detail to allow Petitioners to object that "lip smacking" is more properly correlated with CNS inhibition, and to supplement the objection with the published literature studies they cite here. *See, e.g., Forest Guardians v. US Forest Service*, 495 F.3d 1162, 1170-1172 (10th Cir. 2007) (Claim held waived where comments "failed to present its claims in sufficient detail to allow the agency to rectify the alleged violation"); *National Association of Manufacturers v. US DOI*, 134 F.3d 1095, 1111 (DC Cir. 1998) ("We decline to find that scattered references to the services concept in a voluminous record addressing myriad

complex technical and policy matters suffices to provide an agency like DOI with a 'fair opportunity' to pass on the issue.") For the reasons discussed in Unit VI.C, EPA considers the objection and evidence untimely, and therefore waived. As such, this objection does not warrant a hearing.

But in any event, this issue is not material. EPA's decision to retain a 4X children's safety factor did not rest exclusively, or even significantly—on the effects observed in this developmental study. Rather, EPA retained the children's safety factor based on the lack of data in the PNS and/or a surrogate at the low end of the response curve, and the fact that the available pup RBC data at higher doses affirmatively indicate that the PNS appears to be significantly more sensitive than the CNS (73 FR 44871-44872; 74 FR 23073-23075). Indeed, it is clear from both the proposed and final rules that the results of this study merely supplemented the Agency's bases for concern (73 FR 44871-44872; 74 FR 23073-23075). The Petitioners' complaint that the effects occurred at dose levels three times higher than PoD and therefore do not quantitatively support the 4X children's safety factor is equally immaterial. The record is clear that EPA relied on comparisons between the $BMD_{50}$ estimated for pup brain and RBC AChE inhibition to derive the 4X (73 FR 44871-44872; 74 FR 23073-23075). A hearing can only be based on a genuine issue of disputed fact. Where a party's factual allegations are contradicted by the record, there is no genuine dispute (40 CFR 178.32(b)(1)) (*See*, 73 FR 42683, 42701 July 23, 2008; 57 FR 6667, 6672, February 27, 1992) ("A hearing must be based on reliable evidence, not on mere allegations or

on information that is inaccurate and contradicted by the record.").

*iii. Denial of objection.* The carbofuran developmental study does not definitively resolve whether the effects described were the product of PNS or CNS AChE inhibition; because only RBC AChE inhibition data were collected it is not possible to determine the degree of CNS inhibition. However, as the Petitioners acknowledge, chewing or oral fasciculations, which are the movements EPA described at the SAP meeting and in the proposed and final rules, have often been reported as an early sign of toxicity produced by carbamates and OPs in rats (Exhibit 5 at 2). Petitioners also acknowledge that "oral fasciculations" are indeed a peripheral neuromotor response (Id.) ("some of the toxicity is peripherally mediated or an effect on the PNS (for example, muscle fasiculations and tremors are due to inhibition of AChE at the motor endplate of the muscle)"). Nevertheless, Petitioners attempt to confuse the issue by providing several different descriptions of oral movements, from lip-smacking to mouth smacking to mouth movements to chewing movements, and claiming that it is clear that these are all CNS effects. As an initial matter, it is unclear whether all of the study authors in Petitioners' cited literature are referring to the same phenomenon. It is therefore unclear whether the oral movements from the carbofuran developmental study (which EPA described as "lip-smacking" and "fasiculations") are the same responses described as "tongue protrusion," "gaping," "yawning," and "chewing movements" in the pharmacology papers Petitioners reference. It is not unlikely that all of the different papers refer to

somewhat different actions; Rupniak *et al.* (Ref. 68) were able to produce "chewing jaw movements" by chronic treatment with haloperidol, a dopaminergic receptor antagonist, which suggests that the movements studied in that paper are not purely cholinergic. The fact that anticholinergics could block the haloperidol-induced dopaminergic movements shows that this is not a straightforward physiological response dealing only with the cholinergic system. For the same reason, this calls into question the contention that the effects are exclusively CNS-related.

Similarly, the claim that the "the masticatory response" is clearly a CNS effect is equally misleading and inaccurate. The report in Exhbit 5 claims that "[t]he masticatory response is considered a preliminary index of convulsive activity and convulsions have been demonstrated to be caused by changes in brain chemistry." None of the papers the Petitioners cited describe this "masticatory response" in that way. Instead, those papers all state that this response is seen at relatively low doses of these anticholinesterases. By way of contrast, convulsions are seen at high doses. The Exhibit also implies that the "masticatory" response and convulsions are a continuum of the same phenomemon; however EPA is aware of no scientific support for this claim, and Petitioners have provided none.

Petitioners' objection on this issue is therefore denied.

The Exhibit also implies that the "masticatory" response and convulsions are a continuum of the same phenomemon; however EPA is aware of no scientific support for this claim, and Petitioners have provided none.

d. *Objection/hearing request subissue: EPA's analysis does not rely on Good Laboratory Practice (GLP)-compliant studies.* Petitioners object that EPA's reliance on the ORD data is problematic because the data were not conducted in accordance with EPA's GLP regulations at 40 CFR part 160.

*i. Background.* The only data available on the effects of carbofuran on the pup PNS are RBC AChE inhibition data from two studies conducted by EPA–ORD. These data unequivocally show that pup RBC AChE is more sensitive than pup brain AChE. EPA also used these data in its calculations supporting the 4X children's safety factor. In their comments on the proposed rule, Petitioners alleged that, "the Moser study may not meet minimum criteria for scientific acceptability." They based this on a claim that critical data were unavailable for this study, including: A complete protocol, analysis of dosing solutions, clinical observations, standardization of brain and RBC AChE results in terms of amount per unit of protein, and quality assurance records of inspections for the carbofuran portion of the study. However, no more specific explanation was provided as how this purportedly missing data rendered the data scientifically deficient. EPA responded in full to these allegations in the final rule and response to comments document.

EPA's regulations at 40 CFR part 160 establish a set of principles that provides a framework within which laboratory studies are planned; performed, monitored, recorded, reported, and archived. GLP helps assure EPA that the data submitted are a true reflection of the results obtained during the study and can therefore be relied upon when making risk/safety

assessments. The regulations are applicable only to studies that support, or are intended to support applications for "research or marketing permits" for pesticides regulated under FIFRA (40 CFR 160.1(a)).

*ii. Denial of hearing request.* On several grounds, a hearing on this subissue is not warranted. First, this objection fails to identify a dispute of material fact. There is no dispute that the EPA–ORD studies were not conducted in strict accordance with EPA's GLP regulations. Nor have Petitioners identified a substantive flaw in those studies that they believe resulted from the lack of compliance with the regulations, or otherwise challenged the scientific validity of those studies. Thus, the only issue presented is whether EPA should rely on otherwise scientifically valid studies that were not conducted in accordance with its GLP regulations. This is clearly a legal or policy issue. Hearings are not appropriate on such issues; issues of fact, not of law or policy are required to justify a hearing (40 CFR 178.32(b)(1)).

A further defect is that Petitioners have submitted no evidence on this point. In fact, this claim consists of nothing more than the bare statement that EPA's analysis does not rely on GLP-compliant studies. A hearing will not be granted on "mere allegations" or "general contentions" (40 CFR 178.32(b)(2)). To the extent the Petitioners are relying on the information submitted as part of their comments on the proposed rule, this does not cure the defect, since no substantiating information or other evidence was presented in support of their comments. Nor can simple reiteration of a comment made on the proposed rule justify a hearing. EPA responded to these comments in the final rule, and by ignoring the EPA's

final rule on this subissue, Petitioners have failed to lodge a relevant objection. Both EPA and FDA precedent make clear that when the agency substantively responds to comments on the proposal, the commenter may only keep that issue alive in its objections by addressing the agency's substantive response. *See, e.g.*, 73 FR 42701 (denying hearing because NRDC merely repeated its assertion that the study was not representative from its petition, rather than objecting to the basis EPA asserted in its petition denial for concluding that the study was representative).

Indeed, this entire objection is not material. The EPA-ORD data are the only valid pup RBC data using carbofuran; in the absence of these data, EPA would have no data that would provide relevant information on carbofuran's effects on children's PNS. Under such circumstances, EPA would be required to retain the statutory default 10X, because there would be no "reliable data" on which to base any other factor.

*iii. Denial of objection.* The mere fact that a study is not conducted in accordance with EPA's GLP regulations does not mean that the study is scientifically invalid, or that EPA is prohibited from considering the study. The GLP regulations do not apply to EPA-ORD generated data, but rather to studies conducted to "support applications for research or marketing permits for pesticide products" (40 CFR 160.1(a)). Moreover, the regulations establish general practices; they do not identify the only good laboratory practices that will result in scientifically valid data. Other laboratory protocols, such as that used by EPA-ORD are equally valid. In recognition of this fact the regulations do not prohibit EPA from considering

studies that were not conducted in accordance with EPA's GLP regulations, but merely provide that EPA may refuse to consider such studies to be "reliable" (40 CFR 160.17(a)).

Nor does compliance with EPA's GLP regulations guarantee the validity of the study's results. The RBC data from FMC's carbofuran CCA studies, which were conducted in accordance with EPA's GLP regulations, were unanimously determined to be scientifically invalid by the FIFRA SAP (Ref. 36).

Any claim that the conduct of the EPA-ORD studies raised questions as to their scientific validity is equally baseless. EPA's ORD data were reviewed by the FIFRA SAP, which concluded that, "EPA-ORD has provided excellent data regarding RBC AChE inhibition by carbofuran" (Ref. 36 at 55).

As EPA explained in response to the Petitioners' comments, all of the information the Petitioners claimed was missing had been previously made publically available as part of the SAP review of the carbofuran NOIC, and was provided again in response to FMC's FOIA request. A complete study protocol, as well as a report of the quality assurance (QA), technical, and data reviews of the study, were available, which demonstrated that the procedures and documentation are in accordance with the National Health and Environmental Effects Laboratory (NHEERL)/ORD Quality Assurance Management Plan. Concerning standardization of brain and RBC AChE in terms of protein concentration, the Agency notes that this analysis has not been performed or provided in all the studies on the record, including those sponsored by FMC. However, in the Moser study (Ref. 56), the AChE activity was standardized in

terms of tissue weight per ml, so the amount of protein was consistent across samples, which is an acceptable and widely used practice. Further, abnormal (or "clinical") observations were recorded when they occurred, although the animals could not be watched while they were in the motor activity chambers. Finally, the registrant is correct that the dosing solutions for the comparative ChE study were not analyzed, but ORD performed this analysis for the adult studies in McDaniel *et al.* (Ref. 54), and the preparation and stability of the carbofuran samples were confirmed therein. For these reasons, this objection is denied.

*e. Objection/hearing request subissue: Consistency of EPA's approach to deriving the carbofuran children's safety factor—i. Background.* The Petitioners argue that EPA's approach to deriving carbofuran's children's safety factor is inconsistent with that Agency's approach in deriving the safety factors for other NMC chemicals. Specifically, they point to carbaryl, which had a safety factor of 1X.

Petitioners raised this issue in their comments on the proposed rule. In the final rule, EPA explained at length, the basis for its conclusion that the available data using carbaryl, provided by the carbaryl registrant, supported a finding that a 1X children's safety factor would be "safe" (74 FR 23058 and Ref. 85). EPA explained that the different safety factors established for carbaryl and carbofuran resulted from differences in the chemicals themselves, as reflected by the available data (Id).

*ii. Denial of hearing request.* A hearing is not appropriate on this objection because it raises a legal or policy claim, rather than a dispute as to a material issue

of fact. The claim that EPA acted inconsistently in assessing different pesticide chemicals is purely a legal issue. There is no factual dispute that EPA established a children's safety factor of 1X for carbaryl, and a safety factor of 4X for carbofuran. The only dispute concerns whether EPA's basis for distinguishing between the two is reasonable, and this is a legal claim, on which a hearing is not appropriate (40 CFR 178.32(b)(1)).

In addition, the Petitioners make no claim other than to reiterate the allegation made in their comments on the proposed rule, that EPA's assessment of carbofuran is inconsistent with its assessment of carbaryl. Consequently, Petitioners' objection on this subissue is irrelevant, and therefore immaterial, with regard to EPA's final tolerance revocation regulation because Petitioners ignored EPA's extensive analysis of this issue in the final rule and refiled their comments on the proposal as if EPA's determination in the final rule did not exist. By ignoring the EPA's final rule on this subissue, Petitioners have failed to lodge a relevant objection. Nor have they proffered any evidence in support of this claim. When EPA responds to a comment in the final rule, mere reiteration of the comment in objections does not present a live controversy unless the objector proffers some evidence calling EPA's objection into question (*See, e.g.*, 73 FR 42700-42701).

*iii. Denial of objection.* Carbaryl was evaluated no differently than carbofuran. The different children's safety factors applied to each chemical reflects the differences in the chemicals themselves, as reflected by the data.

It is typical EPA practice to use the central estimate on the BMD as an appropriate measure for comparing chemical potency and the lower limit on the central estimate (*i.e.*, BMDL) as an appropriate measure for extrapolating risk. In the case of carbaryl, the Petitioners inappropriately focused on the $BMDL_{10}$, instead of the $BMD_{10}$. The more appropriate comparison is between the $BMD_{10}$; the carbaryl brain $BMD_{10}$ is 1.46 mg/kg compared with the RBC $BMD_{10}$ of 1.11 mg/kg. As such, the brain to RBC ratio is 1.3X. Therefore, for carbaryl, the brain and RBC AChE data are similarly sensitive. When the tissues are similarly sensitive, the Agency prefers to use data from the target tissue (*i.e.*, central or peripheral nervous system) rather than data from a surrogate tissue (*i.e.*, RBC). EPA's hazard identification for carbaryl states:

> "Although the RBC $BMDL_{10}$ for the more sensitive PND 11 rat is numerically the lowest (0.8 mg/kg) of the two compartments, biologically the RBC $BMDL_{10}$ is similar to the brain $BMDL_{10}$ (1.1 mg/kg). Since the brain is the target tissue for the NMCs, and the brain $BMDL_{10}$ 1.1 mg/kg is also protective of the surrogate and often more variable RBC ChE measurements ($BMDL_{10}$ 0.8 mg/kg), then the brain $BMDL_{10}$ of 1.1 mg/kg is the appropriate PoD for both children and adults in the carbaryl risk assessment (Ref. 82)."

Thus, for carbaryl, biologically the RBC and brain AChE inhibition were basically equivalent where brain AChE inhibition is a direct measure in a target tissue and RBC AChE inhibition is used as a surrogate for the peripheral nervous system. This is quite different

from the situation with carbofuran where a significant difference was noted between RBC and brain AChE inhibition, showing that RBC AChE inhibition (used as a surrogate for the PNS) is more sensitive.

The approach used for carbaryl—*i.e.*, relying on the central estimate for purposes of comparison across age groups, and using biological compartments and the lower limits for use as PoDs—is being used by EPA in its carbofuran risk assessment. In addition, this approach was used in the NMC cumulative risk assessments (CRA) and single chemical risk assessments for multiple OPs. Thus, the Agency is, in fact, being consistent in its hazard identifications among the AChE-inhibiting pesticides.

With regard to the carbaryl children's safety factor, the available brain and RBC dose-response data in PND11 pups include data from the lower end of the dose-response curves. ORD's comparative ChE data with carbaryl show that at the lowest dose at or near 20% inhibition in brain and RBC AChE were observed. Although not ideal, the carbaryl data provide information closer to the benchmark response of 10%, and therefore allow for a reasonable estimation of the $BMD_{10}$ and $BMDL_{10}$. This is distinctly different from ORD's data with carbofuran in PND11 and PND17 pups where the 50% or greater RBC AChE inhibition was observed at the lowest dose. Accordingly, the objection is denied.

*2. EPA's Mathematical Modeling Underlying the Calculation of a 4X Children's Safety Factor.* Petitioners argue that EPA committed numerous errors in calculating the 4X children's safety factor. First, Petitioners allege that, even assuming that RBC values are relevant, EPA's conclusion that the RBC-

related effects in the relevant studies were four times more sensitive than brain effects is not mathematically supportable. Referencing statistical analyses performed by a contractor, they claim that "[a]t most, the data support a 2X safety factor, based on actual difference between brain and RBC (ranging between 1 and 1.9)."

Second, the Petitioners claim that there are several technical errors in the way EPA conducted the statistical modeling that formed the quantitative support for the 4X children's safety factor. They also object that the mathematical assumptions underlying EPA's modeling are not justified and fail to support the 4X children's safety factor. In this regard, they allege that EPA's children's safety factor was based on calculations that (i) are not based on "within animal comparisons;" (ii) have been applied incorrectly and inconsistently to the data, which exaggerated the difference; (iii) overstate the evidence for higher relative RBC sensitivity; and (iv) treated carbofuran inconsistently as compared to other NMCs. They claim that by removing the inconsistencies from EPA's data, the data yield a brain/RBC ratio of 1.3, which confirms Petitioners' approach. These five allegations are addressed separately below.

In support of these claims, the Petitioners offer allegations on the points above, referencing two memoranda from Drs. R. Sielken and C. Valdez-Flores (Exhibits 7, 8, 9) that generally describe and summarize the analyses and modeling they conducted. The full analyses underlying these memoranda were not included with the objections.

a. Objection/Hearing Request Subissue: Use of Within-Animal Brain to RBC Inhibition Comparisons To Derive the Children's Safety Factor

*i. Background.* In the proposed rule, EPA explained its approach to deriving an alternate to the default 10X children's safety factor. This safety factor was calculated using the ratio of RBC and brain AChE inhibition, using the data on administered dose for the PND11 animals from the EPA–ORD studies and the FMC studies combined. In other words, EPA estimated the $BMD_{50}$ for PND11 animals for RBC and brain from each quality study and used the ratio from the combined analysis, resulting in a $BMD_{50}$ ratio of 4.1X. EPA estimated the RBC to brain potency ratio using EPA's data for RBC (the only reliable RBC data in PND11 animals for carbofuran) and all available data in PND11 animals for brain. EPA's approach yields a ratio of about 4 fold.

EPA also compared the $BMD_{50}$ ratios for PND17 pups (who are slightly less sensitive than 11-day olds) in the EPA-ORD study, to confirm that the observed differences in sensitivity between RBC and brain were not unique to the PND11 data. The result of EPA's modeling showed a $BMD_{50}$ ratio of 3.3[13] between brain and RBC in the PND17 pups.

In their comments on the proposed rule, Petitioners presented essentially the same arguments raised in this objection. They argued that a more plausible and straightforward approach would be to compare the

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[13] EPA corrected a technical error identified in Petitioners' comments, which resulted in a revised ratio of 2.6X, for the final rule.

RBC and brain AChE levels at the same time in the same rat when these rats are exposed to carbofuran. The comments claimed that a statistical evaluation of the experimental data on AChE inhibitions in RBC and brain in rats due to carbofuran exposure had been performed by Sielken & Associates, which showed that the percentage inhibition of RBC AChE in a rat is almost the same as the percentage inhibition of brain AChE in the rat. Although the results of the statistical analyses were summarized in the comments, the underlying analyses were not submitted.

In the final rule, EPA provided a detailed explanation of its rationale for rejecting the Petitioners' approach (74 FR 23055; Ref. 85).

*ii. Denial of hearing request.* EPA is denying Petitioners' request for a hearing on this objection for two reasons. First, as in its comments, Petitioners failed to submit the underlying modeling conducted in support of its assertions. Petitioners' consultant merely asserts that the results are as presented in his summarized testimony. In the absence of the underlying scientific analyses, these are effectively no more than mere allegations or general contentions. Hearings will not be granted on this basis alone. (40 CFR 178.32(b)(2); see also 73 FR 42702 (July 23, 2008)(denying NRDC's hearing request on objection that EPA's risk assessment was inadequate because EPA lacked data on how pest strips were used in their homes, because "NRDC provided no factual information to support its claim"); 68 FR 46403, 46406-46407 (August 5, 2003) (FDA denied a hearing involving a challenge to FDA's reliance on consumption pattern data because the objector "did not present any specific information to dispute P & G's consumption

pattern data; instead, [objector] simply asserted that other consumption patterns were likely."); *accord Community Nutrition Institute v. Novitch*, 773 F.2d 1356, 1363 (DC Cir. 1985) ("Mere differences in the weight or credence given to particular scientific studies * * * are insufficient [to show a material issue of fact for a hearing].")).

Second, Petitioners' hearing request is inadequate because they do not object to the basis EPA asserted in the final rule for rejecting this approach. Specifically, Petitioners do not challenge EPA's conclusion that their suggested approach is fundamentally flawed in several regards, nor proffer evidence in support of that challenge. Petitioners also do not challenge EPA's analyses, showing that the results of their suggested approach are in fact consistent with EPA's conclusions. As a consequence, Petitioners' objections are irrelevant, and therefore immaterial, with regard to EPA's final tolerance revocation regulation. The statute, however, requires that objections be filed on the final rule not the proposal. By ignoring the EPA's final rule on this subissue, Petitioners have failed to lodge a relevant objection. Prior FDA decisions under its regulations are instructive here. Objections and hearing requests were filed in response to a food additive regulation covering the irradiation of poultry. (62 FR 64102 (December 3, 1997)). The objector argued that the addition of an anti-oxidant (ethoxyquin) to irradiated chicken prior to the chicken's use in animal feeding studies compromised the studies because the ethoxyquin would have decreased the level of lipid peroxides in the chicken to levels found in chicken that had not been irradiated. The FDA noted, however,

that it had considered the question of ethoxyquin's effect on lipid peroxide levels in the final rule and determined that while ethoxyquin can retard the normal oxidation of chicken fat to peroxides, ethoxyquin cannot reverse oxidation that has already occurred. FDA denied the hearing request reasoning that because the objector did "not dispute FDA's explanation in the final rule as to why addition of ethoxyquin did not compromise the CIVO studies, and provided no information that would have altered the agency's conclusion on this issue * * * there is no factual issue that can be resolved by available and specifically identified reliable evidence" (62 FR 64105). *See also* 53 FR 53176, 53191 (December 30, 1988) (FDA denied a hearing request noting that given FDA's prior conclusion that the studies relied upon by the objector were unreliable, the "burden shifted to [the objector] to maintain the viability of its objection by proffering some information that called into question the agency's conclusion on this matter."). Similarly, here, Petitioners have not challenged the basis EPA asserted for rejecting their suggested within-animal analyses, nor have they proffered any information calling into question EPA's conclusion.

*iii. Denial of objection.* EPA notes that the Petitioners recommended this approach of comparing the degree of inhibition for each animal as part of their presentation to the carbofuran SAP. EPA also addressed this approach, comparing RBC to brain in the same animals, at the SAP and in the responses to the SAP report (Ref. 83). It is notable that the SAP did not endorse this approach (Id.).

EPA's analyses of the Petitioners' approach identified several significant deficiencies. First, the

comparison suggested by the Petitioners would require that EPA ignore existing data. This is because only EPA's study of PND 11 animals contains both brain and RBC data, so the comparisons suggested by the commenter can only be made using that dataset. However, the dose levels in that study were so high that the lower portion of the dose-response curve was missed. At these higher doses, there is little difference between the levels of brain and RBC inhibition. This phenomenon—*i.e.*, that the relative sensitivity of RBC compared to brain appears smaller at higher doses—is also shown in multiple chlorpyrifos studies where blood or peripheral measures of AChE inhibition are more sensitive than brain at low to mid doses, but the tissues appear to be similar at higher doses.

Second, the Petitioners' approach is fundamentally flawed. The Petitioners' suggested alternative relies exclusively on comparisons between the degree of inhibition in the treated animals without any regard to the doses at which the effects occurred. For example, one animal may have shown, on average, 10% inhibition in the brain, when it demonstrated 20% RBC inhibition. Under this approach, what would be relevant would simply be the ratio of 1:2. But the Agency believes it is critical to focus on the ratios of potency, which is the ratio of the doses in the data that cause the same level of AChE inhibition. The Agency's approach of comparing potencies is more directly relevant for regulatory purposes than comparisons of average inhibition. This is because dose corresponds more directly to potential exposures, which is what EPA regulates (*i.e.*, how much pesticide residue does a child ingest). By comparison, the Petitioners' suggested reliance purely on the average degree of

inhibition provides no information that corresponds to a practical basis for regulation.

Finally, the range of ratios of effects that the Petitioners propose as an alternative is consistent with range of potencies that EPA has calculated *at these higher doses*, so the Petitioners' results do not ultimately contradict EPA's assessment, which is intended to account for the effects at lower doses. Briefly, if the dose-responses for RBC and brain inhibition were linear, ratios of inhibition would equal ratios of BMDs. However, these dose-responses are not at all linear; rather the available data demonstrate that brain and blood dose-responses have somewhat different shapes. Thus, estimates of relative effects at particular, relatively high, doses will not determine the estimated ratios at lower doses. This is because the dose-response curves begin to level off as they reach maximal inhibition (*i.e.*, no more inhibition is possible), so, at high doses, there is almost no difference between the ratio of brain and RBC inhibitions. Except at the lowest dose, which produced 50% AChE inhibition, where the ratio is slightly greater than 2, the remaining ratios are only slightly greater than 1. Given the inevitable statistical noise in these measures, it is clear that the ratios expected from EPA's modeling are substantially similar to the results the Petitioner finds in its comparison between individuals. Accordingly, the Petitioners' suggested comparisons at higher doses provide no evidence of what occurs at lower doses; and thus provides no evidence that demonstrates that EPA's modeling results at lower doses is inaccurate.

*b. Objection/hearing request sub issue: Scientific validity of EPA's approach.* The Petitioners object

that EPA's approach has not been established as scientifically valid. They claim that data for other carbamates suggests that $BMD_{50}$ s for the carbamates tend to diverge more than the dose levels used to select the PoD (*i.e.*, the $BMD_{10}$ s). In addition, they criticize EPA's approach for incorrectly assuming that the relationship between $BMD_{50}$ s and $BMD_{10}$ s is linear, which they claim overstates the potential differences. They claim that these issues could be avoided by adopting their suggested approach of using within-animal comparisons to determine the relative sensitivity of RBC and brain AChE. The evidence submitted in support of this subissue is the summary presented in the objection.

*i. Background.* In the proposed rule, EPA explained that its comparisons of the $BMD_{50}$ s for brain and blood relied on an assumption that the magnitude of the difference between RBC and brain AChE inhibition is constant across dose. In other words, EPA assumed that the RBC and brain AChE dose curves are parallel, even though there are no data to test this assumption (73 FR 44873). In their comments, the Petitioners criticized EPA for this assumption, and recommended using "within animal comparisons" to avoid having to make this assumption. In the final rule, EPA explained that its decision to rely on comparisons of $BMD_{50}$ s rather than $BMD_{10}$ s was because the RBC data for 10% inhibition levels was insufficient to allow the Agency to generate the necessary estimates. EPA agreed that the dose-response curves were not parallel at these lower doses, (*i.e.*, that the relationship between $BMD_{50}$ s and $BMD_{10}$ s was not linear) but that EPA lacked any data that would allow it to make

any other assumption. EPA nevertheless rejected the Petitioners' suggested approach of relying on within-animal comparisons, because, as described in the preceding objection, it is intrinsically flawed and scientifically invalid.

*ii. Denial of hearing request.* A hearing on this subissue is not appropriate because Petitioners' request is based on mere allegations, general contentions, and speculation (40 CFR 178.32(b)(2)). No evidence has been submitted on any of the issues raised in this objection. Petitioners have provided no evidence that supports their assertion that EPA's assumption that the dose-response curves will remain parallel at lower doses overestimates the ratios. In the absence of data at the low end of the dose-response curve, which Petitioners were required to have developed, there is just as great a likelihood that EPA's assumption underestimates the ratios. Petitioners have not cited to any data from other carbamates to support their contention that $BMD_{50}$ s tend to diverge more than $BMD_{10}$ s; the objection fails to even identify the carbamate chemicals that purportedly support this claim. Further, the claim is untimely, as it was not raised as part of their comments on the proposed rule. For the reasons discussed in Unit VI.D, EPA will not consider such information in support of a request to justify a hearing.

In addition, a hearing on this objection is denied on the ground of materiality (40 CFR 178.32(b)(1)). In the absence of EPA's assumption, EPA would have no basis for deriving an alternate children's safety factor. Thus, EPA would have to raise the children's safety factor from 4X to the statutory default of 10X, rather than to lower the factor as the Petitioners seek. As

discussed at length in the preceding objection subissue, the Petitioners' suggested alternative of within-animal comparisons is scientifically invalid, and provides no useful basis for regulatory action. Accordingly, if Petitioners establish that available information does not support EPA's assumption that the dose-response curves are parallel, then EPA is left with no valid scientific information to determine the correct dose-response curve at lower doses, or to establish a $BMD_{10}$ (21 U.S.C. 346a(b)(2)(C)). Because deviation from a 10X children's safety factor requires some "reliable data" on the shape of the dose response curve for RBC AChE, Petitioners' objection on EPA's low dose-response curve assumptions, in combination with the failure to provide a valid alternate approach would result in a higher children's safety factor, and a conclusion that EPA has underestimated carbofuran's risks.

*iii. Denial of objection.* EPA disagrees that its approach is not scientifically valid. The models used to develop the BMD estimates have been repeatedly reviewed and approved by the SAP (Refs. 34, 35). The most recent occasion was the February 2008 carbofuran SAP, which concluded that "[t]he dose-response analysis done by the Agency for the EPA–ORD PND11 study was appropriate and led to a very uncertain $BMD_{10}$ * * * This [assumed dose-response] curve fit well in the region where there were data, but there was no way to validate it at low doses" (Ref. 36 at 54).

EPA acknowledges that it lacks information to confirm its assumption that the dose-response curves remain parallel at lower doses. EPA believes this is the most reasonable assumption, given the absence of

information at low doses, since it neither presumes that RBC inhibition will increase or decrease at lower doses. Contrary to Petitioners' naked assertion that EPA's approach overestimates the difference, there is no inherent reason to expect that EPA's assumption would overestimate or underestimate the difference between $BMD_{50}$ s and $BMD_{10}$ s. If indeed data were to show that EPA's assumption overestimated the difference-and Petitioners have submitted none-it would only be as a result of the animal biology, as there is no indication in the mathematical modeling that it overestimates the difference in any way. The mathematical relationship between $BMD_{50}$ s and $BMD_{10}$ s certainly provides no hint that there might be a bias. In this regard, it is notable that the February 2008 SAP concluded that '[w]hat the Panel observed at the low end [of the dose-response curve] made it tempting to assume linearity at this part of the dose-response curve" (Ref. 36 at 55).

Regarding the Petitioners' claim that data for other carbamates suggests that $BMD_{50}$ s for the carbamates tend to diverge more than the dose levels used to select the PoD (*i.e.*, the $BMD_{10}$ s). EPA cannot confirm the accuracy of this allegation, as Petitioners have provided neither data nor any explanation of a biological basis to support this claim. Nor is EPA able to substantiate this claim based on the information currently available. However, there is no *a priori* reason to expect such a systematic divergence between ratios of $BMD_{50}$'s and ratios of $BMD_{10}$ s for blood and brain, based either on biology or the mathematical relationship between $BMD_{50}$'s and $BMD_{v}$ s. It is actually far more probable that the variation from

chemical to chemical (due both to real variation among chemicals and to statistical sampling noise) would be large enough to make a conclusive determination from data difficult.

*c. Objection/hearing request sub issue: Combining data from different toxicological studies—i. Background.* In its risk assessment, EPA relied on all of the valid data from the available studies to calculate the estimates that served as the PoD, and to calculate the estimates of $BMD_{50}$ s that serves as quantitative support for derivation of the 4X children's safety factor.

For purposes of the PoD, the Agency used a meta-analysis that combined valid data from all available studies to calculate the $BMD_{10}$ and $BMDL_{10}$ for pups and adults; this analysis includes brain data from studies where either adult or juvenile rats or both were exposed to a single oral dose of carbofuran. The quality brain AChE data from the three studies (2 FMC, 1 EPA-ORD) conducted with PND11 rats, in combination, provides data to describe both low and high doses. By combining the three studies in PND11 animals together in a meta-analysis, the entire dose-response range is covered.

EPA also combined studies in calculating the 4X children's safety factor. EPA derived the ratio of RBC and brain AChE inhibition using the data on administered dose for the PND11 animals from the EPA-ORD studies and the FMC studies combined. In other words, EPA estimated the $BMD_{50}$ for PND11 animals for RBC and brain from each quality study and used the ratio from the combined analysis, resulting in a $BMD_{50}$ ratio of 4.1X. EPA estimated the RBC to

brain potency ratio using EPA's data for RBC (the only reliable RBC data in PND11 animals for carbofuran) and all available data in PND11 animals for brain.

In their comments on the proposed rule, Petitioners claimed that EPA's decision to combine data for different strains of rats, sexes, experiments, laboratories, dates, dose preparations, rat ages, and times between dosing and AChE measurement, is problematic, claiming that these differences in study design severely limit the validity of EPA's comparisons. Further, they alleged that differences in data and methods EPA used to estimate its $BMD_{50}$ (brain) and $BMD_{50}$ (RBC) caused EPA to overestimate the difference between brain and RBC, and thereby invalidating any comparison of the estimates. Specifically, Petitioners were concerned that the datasets from the six studies EPA used for brain differ not only because they were from different studies, but also because the data were taken at different times ranging from 15 minutes to 4 hours after dosing.

EPA responded to these comments in full during the rulemaking (74 FR 23055-23057 (May 14, 2009); Ref. 85). Petitioners referenced these comments in their objections, but presented no further argument or evidence on any of these points. Because Petitioners originally raised this claim also with respect to the derivation of EPA's PoD, even though they only raise it in this objection here, the Agency responds to both points below.

*ii. Denial of hearing request.* The Petitioners have not met the requirements for a hearing on this subissue. Petitioners have not challenged the basis EPA asserted for rejecting their suggested within-animal analyses, and have therefore failed to lodge a

relevant objection. Both EPA and FDA precedent make clear that when the agency substantively responds to comments on the proposal, the commenter may only keep that issue alive in its objections by addressing the agency's substantive response (40 CFR 178.32(b)(3)). Nor have they proffered any evidence that calls the substance of EPA's conclusions into question. A hearing is not warranted on the basis of mere denials or contentions (40 CFR 178.32(b)(2)). *See* 73 FR 42698-42699 (When an objector does not challenge EPA conclusions in the section 408(d)(4)(iii) order but rather challenges some prior conclusion that was superseded by the section 408(d)(4)(iii) order, the objector has not raised a live controversy as to an issue material to the section 408(d)(4)(iii) order); 53 FR 53176, 53191 (December 30, 1988) (FDA denied a hearing request noting that given FDA's prior conclusion that the studies relied upon by the objector were unreliable, the "burden shifted to [the objector] to maintain the viability of its objection by proffering some information that called into question the agency's conclusion on this matter.")).

Second, this objection is not material. In the case of carbofuran, EPA used a sophisticated analysis of multiple studies and datasets to develop the PoD for the carbofuran risk assessment. Instead of this analysis, EPA could simply have followed the general approach laid out in its BMD policy (Ref. 100), which is used in the majority of risk assessments. Under this general approach, EPA would regulate using the most sensitive effect, study, and/or dataset. If the Agency chose not to combine the data in its analyses, as the commenters' suggested, data collected at or near the peak time of effect (*i.e.*, 30 minutes) would in fact

provide the more relevant datasets. If this more simple approach were taken, in accordance with BMD guidance, EPA would select the lowest $BMDL_{10}$. Assuming the commenters' values were used, EPA would have selected a PoD of 0.009 mg/kg/day, instead of the 0.03 mg/kg/day that EPA is currently using in its risk assessment. A lower PoD of 0.009 mg/kg/day would significantly increase carbofuran's level of estimated risk.

*iii. Denial of objection.* In general, EPA believes that consideration of all available data is the scientifically more defensible approach, rather than the selective exclusion of reliable data. The Agency's Draft BMD Guidance says the following: "Data sets that are statistically and biologically compatible may be combined prior to dose response modeling, resulting in increased confidence, both statistical and biological, in the calculated BMD" (Ref. 76). The SAP has reviewed and approved EPA's practice of combining data from studies numerous times (Refs. 34, 35, 36). Most recently, as part of the carbofuran SAP, the SAP was fully aware that the Agency was planning to derive BMD estimates from data sets using different strains of rats (Ref. 36). Accordingly, the Agency's carbofuran analysis has included all available, valid data in its analysis.

By contrast, the Petitioners' suggested analysis ignores relevant, scientifically valid data. Their analysis left out the 30-minute data from MRID no. 47143705 (Ref. 2), but provided no rationale as to why it would be appropriate to selectively exclude data from the time frame in this study most relevant to the risk assessment (*i.e.*, peak AChE inhibition). The Petitioners' analysis of the individual datasets from

this study showed that at 30 minutes the females and males provide $BMDL_{10}$s of 0.009 mg/kg/day and 0.014 mg/kg/day, respectively. When the datasets were combined, inclusion of the 30-minute timepoint from MRID no. 47143705 decreased the $BMDL_{10}$ from 0.033 mg/kg/day to 0.030 mg/kg/day.

Although the Petitioners complain that EPA's approach of combining data across multiple studies is scientifically inappropriate, the Petitioners themselves combined the results of analysis from four datasets in the information presented with their comments and referenced in their objections. Indeed, it is notable that most of the criticisms raised by the Petitioners also apply equally to the Petitioners' own analysis, as described in more detail in EPA's Response to Comments document (Ref. 85).

The Petitioners are also incorrect that differences in the data available for brain and RBC are so great as to invalidate comparisons of the BMD estimates. EPA used all the data available in each case, and used a hierarchical model to account for variability of the BMD among laboratories for the brain endpoint, which the SAP has explicitly reviewed and approved numerous times (Refs. 34, 35, 36).

The Petitioners are correct that data from both sexes were combined for brain but only male data were used for RBC. However, EPA first performed an evaluation of the differences between the sexes. EPA combined data from males and females only after showing that they did not respond differently.[14] The

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[14] See pp. 34-35 in the brain document dated October 25, 2007 for adults, pp. 47-48 in the same document for PND11 animals; p. 15 in the RBC document dated October 23 for adults.

only remaining study to examine AChE activity in RBC in PND11 animals, after FMC's flawed studies were eliminated, contained only male animals. Both $BMD_{50}$ s for brain and RBC in adults were based on 15 minutes, the minimum time interval after dosing when a sample was taken, in each dataset.[15] This is also true for the brain endpoint in PND11 animals. However, the only study available of the RBC endpoint in PND11 animals was conducted at 40 minutes after dosing, and did not include a recovery time course study.

EPA believes that its decision to combine data for purposes of its $BMD_{50}$ estimates supporting the children's safety factor is equally appropriate, and any differences in the way in which the studies were conducted did not impact the validity of EPA's analyses. For example, one of Petitioners' complaints was that it was inappropriate to combine studies because the data in the studies were taken at different times, ranging from 15 minutes to 4 hours after doses. EPA responded to the allegation that this was problematic by conducting the analysis that the Petitioners claimed should have been done to support this. As explained in the final rule, although EPA disagreed with the Petitioners' contention that this was necessary or appropriate, EPA conducted the Petitioners' suggested analysis, and used the dose-time-response model to extrapolate $BMD_{50}$ s to develop a common point of comparison between all studies. Specifically, EPA extrapolated the PND11

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[15] See Oct. 5, 2007 reports, page 8 (for the values of the time interval) and page 63 (setting the parameter delta to the minimum non-zero value for that interval) in the RBC report, and page 9, and page 45 for the corresponding report for Brain.

brain analysis to estimate $BMD_{50}$ for 40 minutes after dosing for comparison with the existing PND11 RBC $BMD_{50}$, and extrapolated the PND11 RBC $BMD_{50}$ to 15 minutes after dosing for a range of assumed recovery half-lives, for comparison to the existing PND11 brain $BMD_{50}$. The results are provided in (Refs. 24, 25). In either approach, the estimate of the RBC to brain potency ratio in PND11 animals is increased, and EPA's safety factor would correspondingly increase to reflect that larger difference. For example, when the PND11 brain $BMD_{50}$ is extrapolated to 40 minutes, the RBC to brain potency ratio grows to 4.7 (Ref. 24 at 46), and when the PND11 RBC $BMD_{50}$ is extrapolated to 15 minutes, using a range of estimates for the recovery half-life of the RBC endpoint, the RBC to brain potency ratio ranges from 4.2 to 4.6 (Ref. 24). The Petitioners' approach would therefore support a children's safety factor of 5X rather than the 4X EPA is currently applying in its risk assessments. Nevertheless, EPA continues to believe that its current use of a 4X factor reflects the most reliable interpretation of existing quality data.

Although it is true that EPA's $BMD_{50}$ for brain was based on data from 6 datasets while the RBC $BMD_{50}$ was based on a single study, this is because scientifically acceptable RBC data are only available from a single study. As discussed, the fact that EPA used all available data sets in its modeling does not affect the validity of its modeling (Ref. 76).

For all of the foregoing reasons, this objection is denied.

*d. Objection/hearing request sub issue: Technical Flaws in EPA's statistical comparisons.* In their objections, Petitioners claim to have found a number of technical errors and inconsistencies in how the modeling was conducted. Correcting for these errors, they claim, shows that the BMDs for brain and RBC data are essentially the same, which was consistent with the results of modeling conducted by the Petitioners when evaluating the individual animal data. Specifically, Petitioners allege that the approach EPA used to estimate $BMD_{50}$ s for carbofuran is inconsistent with its "meta-analysis" approach of combining studies. The Petitioners also argued that EPA's modeling failed to account for significant difference in study methodologies (*e.g.*, time to sacrifice following dosing). For example, EPA's $BMD_{50}$ (Brain) is calculated at 15 minutes after exposure starts whereas EPA's $BMD_{50}$ (RBC) is calculated at 40 minutes after exposure starts. EPA's $BMD_{50}$ (brain) is based on 6 studies whereas EPA's $BMD_{50}$ (RBC) is based on 1 study, and the dose-time-response modeling methodology for combined studies and EPA's $BMD_{50}$ (brain) is different than the dose-time response modeling methodology for a single study and EPA's $BMD_{50}$ (RBC). Petitioners also allege that EPA applied its dose-time-response model inconsistently between the brain and RBC calculations, alleging that the power was fixed to 1.00 for brain, but estimated for RBC." They also criticize the modeling on the grounds that EPA did not: (1) Account for differences between the combined datasets; (2) develop a protocol supporting its approach; (3) clearly document its method; (4) accurately document model parameters;

(5) rely on a plausible dose-response model, or (6) report its data accurately or transparently. They further allege that "removing all of these inconsistencies in methodology results in a ratio of 1.3, which corresponds with the ratio that the Petitioners claim to have obtained based on their within animal comparisons.

Petitioners have provided neither further details of their concerns than the explanation above, nor any other evidence to support this objection.

*i. Background.* EPA addressed all of the commenters' claimed inconsistencies in its final rule and Response to Comments document (74 FR 23055-23056; Ref. 85 at 61-62). For the majority of these claimed flaws and inconsistencies, EPA explained that the Petitioners had misunderstood EPA's analyses, or that the Petitioners' were incorrect. However in response to certain allegations, EPA conducted new analyses to determine whether the suggested alternative approaches would make any significant difference in EPA's modeling outcomes.

Petitioners have provided little detail in their objections on the issues they intend to raise in their testimony; in most instances, they simply allege that EPA's modeling was incorrect. But as the objections reference the Petitioners' comments on the proposed rule, EPA assumes that they intend to raise only the points previously discussed in their comments.

*ii. Denial of hearing request.* The Petitioners' request for a hearing on the issues raised in this objection is denied on two bases. First, Petitioners have not challenged the substance of EPA's response to their comments or submitted evidence that calls the substance of EPA's conclusions into question. As

previously explained, their failure to challenge the actual basis of EPA's final rule affects the materiality of the objection and hearing request (40 CFR 178.32(b)(3)). *See* 73 FR 42698-42699 (When an objector does not challenge EPA conclusions in the section 408(d)(4)(iii) order but rather challenges some prior conclusion that was superseded by the section 408(d)(4)(iii) order, the objector has not raised a live controversy as to an issue material to the section 408(d)(4)(iii) order) 53 FR 53176, 53191 (December 30, 1988) (FDA denied a hearing request noting that given FDA's prior conclusion that the studies relied upon by the objector were unreliable, the "burden shifted to [the objector] to maintain the viability of its objection by proffering some information that called into question the agency's conclusion on this matter.")). Further, Petitioners have not rebutted, or even acknowledged, the additional analyses EPA undertook at their suggestion, and discussed in the final rule, which ultimately provided further support for EPA's position. For example, in response to the complaint that EPA should have generated a new dose-response model in order to calculate the $BMD_{50}$ s for brain and RBC, EPA conducted the suggested calculation, and under that analysis, the result is the same as that EPA originally calculated. Similarly, in response to the complaint that EPA should have used the dose-time-response model to extrapolate $BMD_{50}$ s to develop a common point of comparison between all studies, EPA conducted that analysis and described it in the final rule (74 FR 23055-23056 (May 15, 2009)). The result of this reanalysis supported a higher children's safety factor than EPA's 4X. But rather than challenge the new analysis, Petitioners simply

repeat the assertions made in their comments. Because the objections on these points fail to account for EPA's analyses, the objections are contradicted by the record, and accordingly, fail to demonstrate a factual dispute (40 CFR 178.32(b)(1)). *See* 73 FR 42698-42699 (Denying NRDC hearing where objection reiterated claims premised on conclusions in EPA's preliminary risk assessment, rather than objecting to EPA's conclusions in the revised assessment prepared for the petition denial); 49 FR 6672 (February 22, 1984) (no hearing if claim based on demonstrably false premise); 57 FR 6667 (February 27, 1992) ("A hearing must be based on reliable evidence, not on mere allegations or on information that is inaccurate and contradicted by the record").

Second, as in their comments, Petitioners failed to submit the underlying modeling they claim to have conducted in support of their objections. Petitioners' consultants merely assert that the results are as presented in their summarized testimony. In the absence of the underlying scientific analyses, these are effectively no more than mere allegation or general contentions. Hearings will not be granted on this basis. (40 CFR 178.32(b)(2); see also 68 FR 46403, 46406-46407 (August 5, 2003) (FDA denied a hearing involving a challenge to FDA's reliance on consumption pattern data because the objector "did not present any specific information to dispute P & G's consumption pattern data; instead, [objector] simply asserted that other consumption patterns were likely."); *accord Community Nutrition Institute v. Novitch*, 773 F.2d 1356, 1363 (DC Cir. 1985) ("Mere differences in the weight or credence given to particular scientific studies

* * * are insufficient [to show a material issue of fact for a hearing].").

*iii. Denial of Objection.* For all of the reasons discussed in the final rule and Response to Comments documents, this objection is denied. A summary of EPA's bases, which were discussed in detail in both the final rule and Response to Comments document, is presented below.

*Consistency of EPA approach.* In their comments, the Petitioners' explained that the alleged inconsistency with which they were concerned was that "EPA attempts to extrapolate a $BMD_{10}$ to a $BMD_{10}$ without refitting the data. That is, EPA uses the dose-response model obtained for the $BMD_{10}$ rather than obtaining a new model for $BMD_{50}$." They claimed this was "especially troublesome since EPA has expressly stated that the model obtained for $BMD_{10}$ (RBC) is unreliable."

The Petitioners' allegation on this point is incorrect. The model itself does not need to change in order to develop a $BMD_{50}$. Whether one wants to estimate the $BMD_{10}$ or the $BMD_{50}$, one would use the same underlying model. EPA simply developed a mathematical expression to adjust parameter values for that fitted model so that, for any given benchmark response level (in particular, for 10% or 50% inhibition), the corresponding BMD could be estimated as a parameter in that model. The same expression makes it possible to compute a BMD for any given response level from estimates based on any other response level. Mathematically, it is not necessary to refit the model to the data to estimate different BMD levels.

However in response to the comments, EPA conducted their suggested calculation, and the ratio of brain to RBC $BMD_{50}$ s in this new analysis is the same as the ratio EPA calculated by using the mathematical expression (Refs. 24, 25). Both provide a ratio of brain to RBCs $BMD_{50}$ of 4X. Specifically, in the just cited documents above, the values are for PND11 brain $BMD_{50}$ are 0.35 (Ref. 24 at 40) and for RBC, 0.086 (Ref. 25 at 20), resulting in a ratio of 4.09.

With regard to the EPA's purported statement that the $BMD_{10}$ model is unreliable, the Petitioners misconstrued EPA's statement. EPA stated that it cannot reliably estimate the RBC $BMD_{10}$ and $BMDL_{10}$ in pups because it lacks data at low doses, not because its model is unreliable. Given the greater amount of data, the estimate for the $BMD_{50}$ is substantially better supported, and thus, less uncertain, than the estimate of the $BMD_{10}$.

*Differences in study methodologies.* Both $BMD_{50}$ s for brain and RBC in adults were based on 15 minutes, the minimum time interval after dosing when a sample was taken, in each dataset.[16] This is also true for the brain endpoint in PND11 animals. However, the only study available of the RBC endpoint in PND11 animals was conducted at 40 minutes after dosing, and did not include a recovery time course study.

As noted in the previous objection response, EPA used the dose-time-response model to extrapolate

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[16] See Oct. 5, 2007 reports, page 8 (for the values of the time interval) and page 63 (setting the parameter delta to the minimum non-zero value for that interval) in the RBC report, and page 9, and page 45 for the corresponding report for Brain.

$BMD_{50}$ s to develop a common point of comparison between all studies. Using that approach would support a children's safety factor of 5X rather than the 4X EPA has applied.

Although it is true that EPA's $BMD_{50}$ for brain was based on data from 6 datasets while the RBC $BMD_{50}$ was based on a single study, this is because scientifically acceptable RBC data are only available from a single study. As discussed in the preceding objection response, the fact that EPA used all available data sets in its modeling does not affect the validity of its modeling (Ref. 76).

*Inconsistent application of model.* EPA did not apply its model inconsistently; the difference to which the Petitioners refers results from the differences between the available data. In order to generate an estimate of the power parameter, data at both extremes of the dose-response curve are necessary. Despite the comparatively greater amount of brain inhibition data, the brain data did not provide information at both extremes of the curve. A value of 1.00 is the standard default in this situation for all the NMC dose-response analyses. Moreover, despite the limited information at the extremes of the dose-response curve for estimating power in the brain data, a power parameter of 1.00 is consistent with the available brain data. By contrast, because the available RBC data provides the necessary information at higher doses, the power in the RBC data could be directly estimated and was significantly less than 1.0.

EPA is unable to comment on the analyses referenced in the Petitioners' objections as they failed to provide them. However, EPA has previously explained the reasons for rejecting the suggested

analysis based on brain RBC comparisons within the same animal. This is discussed at length in the final rule and response to comments, as well as Unit VI.E.2.a of this Order.

*f. Objection/hearing request sub issue: Consistency in approach between carbofuran and other NMC chemicals—i. Background.* In their comments on the proposed rule, the Petitioners argued that EPA's approach to deriving carbofuran's children's safety factor was inconsistent with its approach to deriving the safety factors for other NMC pesticides. They identified only three specific chemicals: Aldicarb, oxamyl, and carbaryl. With respect to aldicarb they argued that although the relative potency of carbofuran is less than aldicarb, the uncertainty factors assigned by EPA presuppose that carbofuran is ten times more toxic that aldicarb. They claim that the aldicarb data show that by all objective measures of toxicity, aldicarb is nearly twice as acutely toxic as carbofuran across all species tested. They further claim that an alternative approach to relative rankings of carbamates proposed by the SAP in its assessment of the NMCs (which also considered the rate of recovery) also showed aldicarb having approximately twice the potency of carbofuran. They further alleged that the children's safety factor for carbaryl was inconsistent with the safety factor applied to carbofuran. Finally, the Petitioners compared the aPAD, aRfD, and uncertainty factors for oxamyl, aldicarb, and carbaryl, concluding that these were inconsistent with EPA's conclusions for carbofuran.

EPA responded to these comments in both the final rule and the accompanying response to comments document (74 FR 23058 (May 15, 2009)).

In their objections, Petitioners have not identified any specific facts that they believe demonstrate inconsistency. They merely allege that the "relative potency of carbofuran as compared to other N-methyl carbamates does not correspond with OPP's aPAD for carbofuran relative to those same compounds."

*ii. Denial of hearing request.* A hearing is denied on this subissue because there is no disputed factual matter for resolution at a hearing. There is no dispute concerning the children's safety factors that EPA applied to the other carbamates, nor how EPA derived those safety factors. Thus, the only question is whether it was reasonable for EPA to account for the fact that other chemicals had a greater amount of toxicity data, and therefore greater uncertainty, in determining the appropriate children's safety factor, when the statute requires EPA to account for "the completeness of the data" (21 U.S.C. 346a(b)(2)(C)). This question requires the application of a legal standard to undisputed facts. Hearings are not appropriate on questions of law or policy (40 CFR 178.32(b)(1)). *See*, 73 FR 42706-42707) (denying NRDC hearing request when the only question raised was whether a human study using only adult males met the regulatory requirement of "scientifically valid and relevant data". FDA has repeatedly confirmed that the application of a legal standard to undisputed facts is a question of law for which a hearing is not required. (*See, e.g.*, 68 FR 46403, 46406 n.18, 46408, 46409 (August 5, 2003) (whether facts in the record show there is a reasonable certainty of no harm is a question of law; whether a particular effect is a "harm" is a question of law)).

In addition, Petitioners have not challenged the substance of EPA's response to their comments, but simply reiterated their comments on the proposed rule. Accordingly, a hearing is not warranted, as the objection is subissue is irrelevant, and therefore immaterial, with regard to EPA's final tolerance revocation regulation (40 CFR 178.32(b)(3)). *See* 73 FR 42698-42699 (July 23, 2008) (When an objector does not challenge EPA conclusions in the section 408(d)(4)(iii) order but rather challenges some prior conclusion that was superseded by the section 408(d)(4)(iii) order, the objector has not raised a live controversy as to an issue material to the section 408(d)(4)(iii) order; 53 FR 53176, 53191 (December 30, 1988) (where FDA responds to a comment in the final rule, repetition of the comment in objections does not present a live controversy unless the objector proffers some evidence calling FDA's conclusion into question)).

Nor have they submitted evidence that calls the substance of EPA's conclusions into question. Petitioner's entire argument concerning this issue is a single conclusory sentence. A hearing will not be granted on "mere allegations" or "general contentions." (40 CFR 178.32(b)(2)) (See 53 FR 53176, 53199 (December 30, 1998)) ("Rather than presenting evidence, [the objector] asserts that FDA did not adequately justify its conclusions. Such an assertion will not justify a hearing.").

*iii. Denial of objection.* Although it is unclear which precise chemicals the Petitioners believe demonstrate that EPA was inconsistent, the only ones on which any allegations were arguably presented were those identified in their comments on the proposed rule: aldicarb, carbaryl, and oxamyl. Accordingly, EPA

denies this objection for the same reasons that EPA explained in its final rule and comment responses.

In their comments, the Petitioners provided information on the oral $LD_{50}$ in rat and the $BMDL_{10}$ for AChE in rat brain or human RBC. The comments also provided uncertainty factors for the three NMCs, the respective aRfD[17] or aPAD[18] and the cumulative risk assessment oral potency factor. The $LD_{50}$ and $BMDL_{10}$, values provided are not completely accurate.

The allegations and the supporting information contained in Petitioners' comments were inaccurate. For example, the $LD_{50}$ values in the oxamyl RED were 3.1 mg/kg (male) and 2.5 mg/kg (female), rather than 30 mg/kg as the Petitioners claimed. Further, the Agency's recent hazard assessments of carbaryl and aldicarb are each consistent with EPA policies and practice, as well as with the Agency's approach to the assessment of carbofuran.

The Petitioners' assertions regarding aldicarb were based on an earlier assessment. At the time the Agency conducted the assessment to which the commenters refer, the Agency was unaware of the difference in sensitivity between PND17 and PND11 animals. Since EPA became aware of the differences, EPA has required the aldicarb registrant to conduct a CCA study in PND11 rats; the Agency anticipates the receipt of this study and the companion range-finding and time course studies in 2009. In the absence of

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[17] aRfD is the acute reference dose.

[18] aPAD is the acute RfD adjusted for the Children's Safety Factor.

these data, EPA will apply the statutory default children's safety factor to account for the additional sensitivity of PND11 animals, because the Agency lacks any "reliable data" that could be used to derive a reduced factor that EPA could determine will be "safe for infants and children."

With regard to the carbaryl children's safety factor, the available brain and RBC dose-response data in PND11 pups include data from the lower end of the dose-response curves. ORD's comparative AChE data with carbaryl show that at the lowest dose 20% or near 20% inhibition in brain and RBC AChE was observed. Although not ideal, the carbaryl data provide information closer to the benchmark response of 10%, which allows for a reasonable estimation of the $BMD_{10}$ and $BMDL_{10}$. This is distinctly different from ORD's data with carbofuran in PND11 and PND17 pups where 50% or greater RBC AChE inhibition was observed at the lowest dose.

Petitioners' other comparisons are equally inapposite. The $LD_{50}$, $BMDL_{10}$, and relative potency factor from the cumulative risk assessment are each measures of chemical potency. Thus, these calculations provide reasonable comparisons of the relative potency of aldicarb, carbofuran, and oxamyl. However, the Petitioners' allegations were based on comparisons of the aPAD, aRfD, and uncertainty factors, which are not measures of potency and should not be interpreted as such (Ref. 79). The magnitude of the uncertainty factors is intended to account for uncertainty in the available data for a particular chemical. For example, it is standard practice to apply a 10X uncertainty factor for extrapolation from animals to humans when ethically and scientifically sound human data are not

available for the pesticide of interest. And this explains the difference in the uncertainty factors applied to the three chemicals. Deliberate dosing studies in human subjects conducted with aldicarb and oxamyl were reviewed and accepted by the HSRB for both scientific validity and ethical conduct. This is not the case for carbofuran. As discussed below in Unit VI.G, the HSRB concluded that the carbofuran study was not sufficiently scientifically robust for use in the risk assessment. Therefore, there is less uncertainty in the aldicarb and oxamyl risk assessments since quality data are available in humans and the interspecies factor can be reduced or removed for these chemicals. There are no comparable data for carbofuran.

Accordingly, this objection is denied.

*F. Objections to EPA's Drinking Water Exposure Assessments.*

Petitioners raise separate objections to EPA's estimates of drinking water exposures from contaminated ground water and to the estimates from contaminated surface water. In each objection, Petitioners argue that, based on newly proposed restrictions submitted as part of their objections, the exposure estimates will be significantly lower than EPA's estimates in the final rule.

*1. Objections relating to groundwater exposure estimates.* Petitioners raise several challenges to the ground water concentration estimates in the final rule. They allege that EPA's estimates are not based on the best available data, but on obsolete data and overly conservative assumptions that are inappropriate because use has been prohibited in all areas like those seen in these data. The objection also claims that the requirements in the new registration proposals to

require setbacks from all drinking water wells ranging between 100 and 1,000 feet will ensure that all potential groundwater exposures will be below the level of concern. In support of this objection three analyses were submitted in Exhibits 12, 13, and 14.

*a. Objection/hearing request subissue: Reliance on the results of the prospective ground water study (PGW) and historical monitoring to validate groundwater exposure estimates.* The Petitioners object that EPA should not have relied for validation on their PGW study or historical monitoring data. They argue that these data are from a period when use was an "order of magnitude greater." Additionally they allege that all areas like those seen in the PGW have now been removed from the carbofuran label, and so the study results do not accurately reflect current risks. In support of this objection, Petitioners reference their comments on the proposed rule, and Exhibit 12.

*i. Background.* In the proposed rule, EPA relied on a drinking water assessment that used both monitoring data for carbofuran and modeling methods (Refs. 13, 42, 44, 47, 67). Regarding the potential exposure from contaminated groundwater, the Agency concluded that drinking water taken from shallow wells is highly vulnerable to contamination in areas where carbofuran is used around sandy, highly acidic soil, although sites that are less vulnerable (*e.g.*, deeper aquifer, higher organic matter) could still be prone to have concentration exceeding acceptable exposures. EPA concluded that the results of its modeling were consistent with the results of the available monitoring data, including a PGW study conducted by FMC in the

1980s, when scaled to reflect the current lower rates of application (73 FR 44881).

In their comments, the Petitioners complained that EPA's reliance on the PGW was inappropriate because that study no longer reflected current conditions. Petitioners also summarized the results of their "National Leaching Assessment" which used PRZM and "databases specifically created to provide access to all necessary inputs for a national scale PRZM modeling." They claimed that after accounting for the use prohibitions on their September 2008 label, the maximum 1-in-10 year peak concentrations in all potential carbofuran use areas is 1.2-1.3 ppb, while expected concentrations in most areas covered by this assessment are below 1.0 ppb. Neither the "National Leaching Assessment" nor the "National Pesticide Assessment Tool" upon which the assessment appears to have been based, were submitted to EPA as part of the Petitioners' comments.

In the final rule, EPA revised the assessment conducted for the proposed rule in response to the FMC comments submitted during the comment period, which requested cancellation of the use on a number of crops and imposed a number of restrictions intended to address the potential for groundwater contamination. These restrictions included use prohibitions in certain states, and well setbacks. Taking these into account, ground water concentrations were estimated for all remaining crops on carbofuran labels, using two new Tier 2 scenarios. Based on a new corn scenario in Wisconsin, representative of potentially vulnerable areas in the upper Midwest where use remained, EPA estimated one-in-ten year concentrations for ground water source drinking water of 16 to 1.6 x $10^{-3}$ ppb, for

pH 6.5 and 7, respectively. Well setback prohibitions of 50 ft were proposed on the new label for the flowable and granular formulations in select counties in Kentucky (7 counties), Louisiana (1 county), Minnesota (1 county), and Tennessee (1 county). Analysis of the impact of these setbacks for the use on corn indicated that the setbacks would not reduce concentrations significantly at locations where exposure to carbofuran in ground water is of concern because at acid pHs, carbofuran does not degrade sufficiently during the travel time from the application site to the well to substantially reduce the concentration.

EPA concluded that the results of the revised corn modeling were consistent with the PGW. Using higher use rates than currently permitted, the peak concentration measured in the PGW study was 65 ppb; when scaled to current use rates, the estimated peak concentration was 11 ppb. The final rule explained that EPA's modeling is also consistent with a number of other targeted groundwater studies conducted in the 1980s showing that high concentrations of carbofuran can occur in vulnerable areas; the results of these studies as well as the PGW study are summarized in References 13 and 67 (74 FR 23079).

*ii. Denial of hearing request.* For this hearing request, the Petitioners have failed to proffer evidence, which would, if established, resolve a material issue in their favor. First, Petitioners' evidentiary proffer does not support their contention, and consequently, EPA is unable to conclude that there is a reasonable possibility that the issue could be resolved in its favor (40 CFR 178.32(b)(2)). Petitioners' own experts relied on the PGW to validate the modeling submitted in support of this objection and to demonstrate the safety of the

tolerances. The Executive Summary of the National Carbofuran Leaching Assessment states

> "[a] model validation study was conducted in which the results of a prospective groundwater monitoring (PGW) study conducted for cabofuran in Maryland from 1981-1983 were compared to the model simulations that most closely matched the PGW study site in terms of location, soil texture, organic carbon content, and pH. The annual peak concentrations during the simulation are on the order of 9 to 11 ppb, which are similar to the measured concentrations in the PGW study (9 to 10 ppb after adjusting for application rate). The validation provides context that the model predictions are reasonable."

(Exhibit 12 at 7). *See, e.g.*, 57 FR 33244 (July 27, 1992) (Studies cited by NRDC do not provide a basis for the hearing because they "support the [FDA] conclusion in question.").

Second, this objection is premised on inaccurate factual statements that are directly contradicted by the record. For example, the objection disregards the fact that EPA scaled the PGW modeling to reflect the lower current use rates. The Petitioners present no challenge to the methods EPA used to scale the study results; indeed, it is likely that their contractor used the same or similar methodology. Equally, the objection that EPA relied on "historical monitoring data from a period when carbofuran use was an order of magnitude larger" is simply incorrect (Ref. Obj at 40). The monitoring results EPA cited in the final rule were from the 1980s, but the targeted monitoring studies were conducted with the same or lower use

rates as those permitted under the current labeling (74 FR 23085, May 15, 2009). Such a submission is insufficient to justify a hearing (*See*, 73 FR 42696 (July 23, 2008)(denying hearing where objector incorrectly claimed that EPA had failed to rely on DDVP-specific information in making its children's safety factor determination); 57 FR 6667 (February 27, 1992) ("A hearing must be based on reliable evidence, not on mere allegations or on information that is inaccurate and contradicted by the record.")

Further, the Petitioners' misrepresentation of EPA's analyses also affects the materiality of the hearing request (40 CFR 178.32(b)(3)). Even if Petitioners were able to successfully refute the validity of the PGW study, it would not affect the validity of the additional monitoring data cited in the final rule (74 FR 23079 (May 15, 2009)), on which EPA also relied to validate its monitoring. *See*, 49 FR 6672 (February 22, 1984) (challenge to one of five related studies; in the absence of any additional data bearing on the clinical study, the objection constitutes nothing more than an allegation).

Finally, the evidentiary proffered with respect to the Petitioners' allegation that all areas with conditions similar to those found in the PGW have been removed from the label is insufficient to warrant a hearing (40 CFR 178.32(b)(2)). To the extent this allegation is based on the information presented as part of the 2008 comments, this claim was rebutted in EPA's final rule, by the modeling based on the Wisconsin corn scenario, and by the lack of any underlying analyses to support of Petitioners' comments. As explained in the final rule, the information provided is insufficient to allow EPA to confirm the Petitioners' contention that there

is no overlap between use and all potentially vulnerable ground water (74 FR 23061-23062 (May 15, 2009)).

The evidence submitted along with this objection does not cure this defect. The only evidence proffered in this regard is the Petitioners' comments on the proposed rule, and the new analysis submitted in Exhibit 12. As previously discussed, mere reiteration of comments made in response to the proposed rule does not provide an adequate basis for a hearing, unless the objector proffers some evidence calling EPA's conclusion into question. Consequently, Petitioners' submission on this issue is irrelevant and therefore immaterial, with regard to EPA's final tolerance revocation (40 CFR 178.32(b)(3)). The analysis in Exhibit 12 appears to be the National Leaching Assessment described in Petitioners' comments, but modified to account for the proposed amendments submitted as part of the objections. As noted previously, neither the National Leaching Assessment nor the model on which it was based was submitted as part of the comments. Because the National Leaching Assessment was available during the comment period but was withheld, this information is considered to be untimely and the Petitioners have waived the right to rely on it. For the reasons discussed in Unit VI.D, EPA therefore will not consider it as an appropriate basis for justifying a hearing on its final rule. *See* 73 FR 42683, 42696 (July 23, 2008); 72 FR 39318, 39324 (July 18, 2007). Further, for the reasons discussed in Unit VI.C, EPA has determined that objections and hearing requests based on the newly proposed amendments, as well as evidence or analyses premised on those amendments, are irrelevant, and therefore immaterial, to EPA's

determination in the May 15, 2009 final rule that the carbofuran tolerances were unsafe and could not be sustained under FFDCA section 408. Petitioners are actually not objecting to the conclusions in EPA's final rule; rather, they are suggesting that EPA might reach a different result in a different factual scenario. Objections, however, must be directed "with particularity [at] the provisions of the regulation or order deemed objectionable" (21 U.S.C. 346a(g)(2)).

*iii. Denial of objection.* EPA denies this objection on several bases. Based on the information available, and even accounting for the September 2008 geographic restrictions, the Agency cannot confirm the Petitioners' claim that use has been prohibited in all areas with conditions similar to the PGW study. Based on the information that was timely submitted, the only information provided was in map format. While maps are useful for interpreting results, maps alone are insufficient for a thorough evaluation of the Petitioners' claim, in part because of the maps' spatial resolution. The maps submitted were all on a nation-wide scale, which does not provide the level of detail necessary to verify the combination of paramaters (*e.g.*, soil textures, pH) at locations identified as vulnerable. Further, the maps provided by the Petitioner do not represent all carbofuran use patterns. For example, Figure IV-2 on page 42 of the Petitioners' comments does not address the granular use patterns and proposed label prohibitions. In addition, as a general matter, none of the previously submitted assessments provided a comprehensive analysis of the distribution of soil and water pHs for the Midwest, Northwest or any other region of the country where carbofuran use would be permitted on the September 2008 label, or

have the Petitioners provided such an analysis with their objections.

Further, the available scientific information does not support their contentions. EPA examined readily available data with respect to ground water and soil pH in order to evaluate the spatial variability of pH. Data from the USGS and other readily available sources do not necessarily encompass the entire range of ground water pH values present within a state. This is especially true for shallow ground water systems, where local conditions can greatly affect the quality and characteristics of the water. Also, pH in a water body can be higher or lower than the tabulated average values. In addition, average ground water pH values for a given area do not truly characterize the area's temporal and especially spatial heterogeneity. This can be seen by comparing differences in pH values between counties within a state, and by the fact that even within a county individual wells will consistently yield ground water with either above- or below-average pH values for that county. The ground water simulations in Reference 84, Appendix I reflect variability in pH by modeling carbofuran leaching in four different soil and subsurface pH conditions (pH 5.25, 6.5, 7.0, and 8.7), representing the range in the aquifer system in that area. This range also approximates the pH range of natural waters in general. The results of the ground water simulations for corn use showed that a relatively small (0.5) decrease in pH from 7 to 6.5 resulted in an increase in the 1-in-10-year peak concentrations of carbofuran in ground water of 4 orders of magnitude.

The results of EPA's revised corn modeling, based on a new scenario in Wisconsin, are consistent with the results of the PGW study developed by the registrant

in Maryland in the early 1980s. Using higher use rates than currently permitted, the peak concentration measured in the PGW study was 65 ppb; when scaled to current use rates, the estimated peak concentration was 11 ppb. EPA's modeling is also consistent with a number of other targeted ground water studies conducted in the 1980s showing that high concentrations of carbofuran can occur in vulnerable areas; the results of these studies as well as the PGW study are summarized in References 13 and 67. For example, a study in Manitoba, Canada assessed the movement of carbofuran into tile drains and ground water from the application of liquid carbofuran to potato and corn fields. The application rates ranged between 0.44-0.58 pounds a.i./acre, and the soils at the site included fine sand, loamy fine sand, and silt loam, with pH ranging between 6.5-8.3. Concentrations of carbofuran in ground water samples ranged between 0 (non-detect) and 158 ppb, with a mean of 40 ppb (Refs. 13 and 67).

Finally, as discussed above, to the extent this objection relies on untimely information and analyses, and on the newly submitted registration amendments, the objection is denied as irrelevant and immaterial.

*b. Objection/hearing request subissue: Accounting for FMC's label mitigation measures.* Petitioners object that EPA's risk assessment relies on "unrealistic and overly conservative assumptions about potential concentrations," and fails to account for FMC's label mitigation measures. They claim that maximum concentrations of carbofuran in groundwater are expected to be below 1.1 ppb, based on the new proposed geographic restrictions and well setbacks. They allege that, "only permeable soils (*e.g.*, greater

than 90% sand and less than 1% organic matter) with acidic soils and water conditions, and shallow water tables (*e.g.*, less than 30 feet) are vulnerable to carbofuran applications." They also claim that vulnerable groundwater only exists along eastern seaboard, and in select counties in the United States, where use has already been prohibited. They argue that further confirmation is provided by the available NAWQA data, which show that detections of carbofuran are rare, and occur only at low levels except in areas where use is now prohibited. Finally, Petitioners allege that in the specific regions where carbofuran will continue to be used under the revised label, groundwater pH data collected under the USGS NAWQA program demonstrate that the average pH is approximately 7.25, and in most regions, moving two standard deviations away from average, which they claim would capture 95% of all observed values, results in pHs that are still greater than 6.0. According to the Petitioners, under such conditions the combination of hydrolysis and drinking water well setbacks would ensure that any carbofuran that might reach ground water sources would degrade to only *de minimis* concentrations less than or equal to 1.1 ppb.

In support of this objection, Petitioners cite the analyses submitted as part of their comments, and the new analyses in Exhibits 12, 13, and 14. Exhibits 12 and 13 contain the revised modeling of the estimated groundwater concentrations from carbofuran use, based on the label restrictions proposed as part of the objections. Exhibit 14 consists of a statistical summary of groundwater pH statistics from the USGS NAWQA database. Means, standard deviations, and numbers of

groundwater measurements in the database are summarized by state and land use within each state.

*i. Background.* In the proposed rule EPA concluded that drinking water taken from shallow wells is highly vulnerable to contamination in areas where carbofuran is used around sandy, acidic soil, although sites that are less vulnerable (*e.g.*, deeper groundwater, less coarsely textured soils) could still be prone to have concentrations exceeding acceptable exposures (73 FR 44881-44883 (July 31, 2008)). EPA also described the available NAWQA monitoring data, and explained the reasons that the monitoring data tends to underestimate exposure for acute risks, such as those carbofuran presents, and so are not sufficiently robust to be used as an input into a quantitative risk assessment or to serve as a lower bound (73 FR 44880-44881 (July 31, 2008)).

As part of their comments on the proposed rule, FMC requested that EPA amend their registration to include a number of geographic use restrictions and migitation measures intended to address the risks to groundwater. In their comments, Petitioners claimed that "[g]roundwater sources are vulnerable to carbofuran leaching only under certain conditions, namely where permeable soils (*e.g.*, areas with soils greater than 90% sand and less than 1% organic matter), acidic soil and water conditions, and shallow water tables predominate (*e.g.*, where ground water is less than 30 feet)." The commenters claimed that these conditions are rare in areas where carbofuran would be used under the new label proposed as part of their comments. They further asserted that in "most states where carbofuran is used, less than 2% of the entire surface areas possess sandy soil texture" and that "low

pH conditions are not found in carbofuran use areas allowed under the registrant's amended label" (Ref. 18 at 33-34). They described, but did not submit analyses they claimed to have conducted to demonstrate this. The summary consisted primarily of maps depicting areas identified as vulnerable.

On December 24, 2008, FMC again requested that EPA amend their registration to include additional restrictions intended to further mitigate carbofuran's risks to groundwater.

In response to the September 2008 proposed label restrictions submitted as part of the comments, EPA revised its risk assessment to take into account the new geographic restrictions, as well as the proposed risk mitigation measures. Based on its revised assessment, EPA explained in the final rule that it disagreed that the criteria on the September 2008 label defined 100% of the conditions where ground water sources would be vulnerable to carbofuran leaching. EPA noted that no comprehensive analysis had been provided that evaluated how the Petitioners had reached this conclusion. As discussed in greater detail in EPA's Response to Comments, the information provided as part of the Petitioners' comments—primarily maps depicting areas identified as vulnerable—was not sufficient to allow the Agency to evaluate their claim (Ref. 84).

EPA also disagreed that the commenters provided sufficient information to support their general claim that only high pH conditions (pH above 7) existed in all the areas in which carbofuran could be used under FMC's September 2008 revised label. EPA presented its assessment of the newly submitted label in its

Response to Comments document and these issues were addressed in substantial detail there (Ref. 84).

EPA did not evaluate the mitigation measures proposed in the December 24, 2008 submission. The mitigation measures in that submission were incorporated into the measures proposed by the Petitioners as part of their objections on June 30, 2009.

*ii. Denial of hearing request.* EPA is denying the hearing requested on this objection because, in large measure, if not entirely, it rests on the newly submitted mitigation measures accompanying Petitioners' objections. As discussed in Unit VI.C, EPA has determined that these objections do not warrant a hearing because they are irrelevant, and therefore immaterial, to EPA's determination in the May 15, 2009 final rule that the carbofuran tolerances were unsafe and could not be sustained under FFDCA section 408 (40 CFR 178.32(b)(3)). Petitioners are actually not objecting to the conclusions in EPA's final rule; rather, they are suggesting that EPA might reach a different result in a different factual scenario. Objections, however, must be directed "with particularity [at] the provisions of the regulation or order deemed objectionable" (21 U.S.C. 346a(g)(2)). In addition, for the reasons discussed in Unit VI.D, EPA has determined that the new risk mitigation measures are not appropriately considered at this stage of the administrative process, and will not grant a hearing on this basis.

Petitioners' objections provide no further clarification as to what is meant by their claim that EPA's assessment relied on "unrealistic and overly conservative assumptions." Therefore, this objection, and the attendant hearing request, is denied based on

Petitioners' failure to state with "particularity * * * the basis for the objection * * *" (40 CFR 178.25(a)(2)). As Petitioners raised similar allegations in their comments, EPA has assumed that they intended to incorporate all of the issues raised in the comments on the proposed rule.

To the extent this objection relies on the September 2008 mitigation measures, EPA denies the hearing request because the evidentiary proffer in support of this objection is insufficient to warrant a hearing. The record is clear on its face that EPA did account for the mitigation measures in its revised risk assessment supporting the final rule. A hearing can only be based on a genuine issue of disputed fact (40 CFR 178.32(b)(1)). Where a party's factual allegations are contradicted by the record, there is no genuine dispute (73 FR 42701-42702 (July 23, 2008) (Denying NRDC's hearing request where EPA had revised its residential exposure assessment to address the issue complained of); 57 FR 6667, 6668 (February 27, 1992) ("A hearing must be based on reliable evidence, not on mere allegations or on information that is inaccurate and contradicted by the record.")).

The objection also suffers from a further defect; many of the allegations in this objection merely reiterate points Petitioners had raised in their earlier comments. For example, EPA addressed the claim that the NAWQA data from 1993-2006 rarely show detections of carbofuran, and that in "almost every instance" the observed concentrations are low. EPA also addressed the claim that only areas with permeable soils (*e.g.*, areas with soils greater than 90% sand and less than 1% organic matter), acidic soil and

water conditions, and where shallow water tables predominate (*e.g.*, where ground water is less than 30 feet) present significant risks of leaching. As previously discussed, mere reiteration of comments made in response to the proposed rule does not provide an adequate basis for a hearing, unless the objector proffers some evidence calling EPA's conclusion into question (40 CFR 178.32(b)(3)). *See, e.g.*, 73 FR 42701-42702 (July 23, 2008); 53 FR 53176 (December 30, 1988).

The evidence submitted in Exhibits 12-14 does not cure these defects. As a preliminary matter, much of this evidence is untimely. The analyses in Exhibits 12 and 13 appear to be the National Leaching Assessment described in Petitioners' comments, but modified to account for the proposed amendments submitted as part of the objections. As noted previously, neither the National Leaching Assessment nor the model on which it was based was submitted as part of the comments. Certainly, there is no justification for Petitioners' refusal to provide the analyses that were available during the comment period. Because the National Leaching Assessment was available during the comment period but was withheld, this information is considered to be untimely and the Petitioners have waived the right to rely on it. Accordingly, as discussed in Unit VI.D, because this evidence was not presented as part of the Petitioners' comments, EPA considers that the evidence submitted in support of this objection is not appropriately considered as a basis for justifying a hearing on the final rule. *See* 73 FR 42683, 42696 (July 23, 2008); 72 FR 39318, 39324 (July 18, 2007). And in the absence of this evidence, this portion of the objection consists of mere

allegations and denials, which do not warrant a hearing (40 CFR 178.32(b)(2)).

But even assuming that the evidence was appropriately considered, the evidence is insufficient, even if established, to justify the factual determination urged (40 CFR 178.32(b)(3)). Nothing in Exhibits 12-13 provides any information that substantively differs from the information summarized in the comments. Second, even assuming that the analysis in Exhibit 14 is valid, on its face the submission states that the analysis only addresses 95% of the samples chosen by the study; no information was provided to explain how the samples relate to the state or other geographic area in which carbofuran would be used. This is important because NAWQA samples were not evenly distributed across most states, but tended to be concentrated in particular regions; in statistical parlance, the samples were not collected randomly. The maps in Exhibit 14 clearly demonstrate that the study samples were not randomly distributed across the state but were primarily in the southern and eastern portions of each state, even though carbofuran use is not restricted to those portions of the states. In other words, no evidence was provided that would allow the Agency to determine the percentage of the carbofuran use area represented by the 95% of the samples the Petitioners' analysis addressed. Nor was any information provided to document the significance of the remaining 5% of the samples that were not captured by their analysis; for example, although this may have only represented 5% of the samples, it is not clear whether this 5% relates to only 5% of the areas where carbofuran may be used, or whether it actually represent a far greater percentage of the use area.

*iii. Denial of objection.* EPA denies this objection on several bases.

The contention that the NAWQA monitoring data—or indeed any available carbofuran monitoring data—provide an adequate basis for concluding that concentrations will remain low in the areas where use is now permitted is incorrect. The NAWQA program focuses on ambient water rather than on drinking water sources, is not specifically targeted to the high use area of any specific pesticide, and is sampled at a frequency (generally weekly or bi-weekly during the use season) insufficient to provide reliable estimates of peak pesticide concentrations in surface water. For example, significant fractions of the data may not be relevant to assessing exposure from carbofuran use, as there may be no use in the basin above the monitoring site. Unless ancillary usage data are available to determine the amount and timing of the pesticide applied, it is difficult to determine whether non-detections of carbofuran were due to a low tendency to move to water or from a lack of use in the basin. As a consequence, the data do not support relying on the non-detections as a lower bound, or relying on the detections as an upper bound. The program, rather, provides a good understanding on a national level of the occurrence of pesticides in flowing water bodies that can be useful for screening assessments of potential drinking water sources, especially for those assessments concerned with chronic, rather than acute toxicants.

While there have been additional groundwater monitoring studies that included carbofuran as an analyte, there has been no additional monitoring targeted to carbofuran use in areas where aquifers are

vulnerable, and the locations of sampling and the sampling frequencies generally are not sufficient to capture peak concentrations of the pesticide in a watershed or aquifer where carbofuran is used. Capturing these peak concentrations is particularly important for assessing risks from carbofuran because the toxicity end-point of concern results from single-day exposure (acute effects). Pesticide concentrations in ground water are generally the result of longer-term processes and less frequent sampling can often adequately characterize peak ground water concentrations. However, such data must be targeted at vulnerable aquifers in locations where carbofuran applications are documented in order to capture peak concentrations. As a consequence, monitoring data tends to underestimate exposure for acute endpoints.

EPA also disagrees that the Petitioners' criteria of soils composed of 90% sand and less than 1% organic matter, and wells of less than 30 feet define all of the conditions under which ground water sources are vulnerable to carbofuran leaching. No comprehensive analysis was provided evaluating how they reached this conclusion. Although the Petitioners proposed these criteria as restrictions on the carbofuran label, the spatial extent of the label restrictions was not provided. Moreover, as discussed in greater detail in EPA's Response to Comments, the information provided as part of the Petitioners' comments (primarily maps depicting areas identified as vulnerable) was not sufficient to allow the Agency to evaluate their claim (Ref. 84). For example, the percent sand, one of the criteria used in this analysis, varies significantly across a field and the whole range of soil textures may occur at a county-level. The

national map provided purports to represent this parameter and several others aggregated together to identify vulnerable locations. This national-scale map does not provide the level of detail needed to verify the combination of paramters at locations identified as vulnerable.

While the assertion that soils with 90 percent sand are the most vulnerable to leaching is in part true, it is misleading. While many states have only small areas of sandy soils, several of the states in which carbofuran would continue to be used under the Petitioners' proposals have quite extensive areas. For example, according to the Petitioners' own assessment of states with high amounts of carbofuran application (Ref. 6), Texas had 4.2% of soils classified "as sand", Michigan had 21.3% and Nebraska had 26.3%. In addition, the Petitioners' statements imply that soils that are sandy textured define the universe of soil textures that are vulnerable to leaching. It is possible that more fine-textured soils, for example sandy loams or silt loams, could also be sufficiently permeable to result in carbofuran leaching as it has not been established how much of a reduction in leaching might occur as texture becomes finer. Furthermore, finer textured soils tend to have more cracks and root channels and thus are more prone to preferential flow.

Petitioners' claims regarding pH concentrations are also incorrect. As an initial matter, their analysis fails to prove that pH values in all use areas will ensure that concentrations are below the level of concern because the analysis in Exhibit 14 is based on a flawed statistical analysis. The methodology on which the Petitioners relied-the use of the mean minus two standard deviations-to estimate the 5th percentile (*i.e.*,

95% of the samples above the value) of the distribution of ground water pHs in a state depends strongly on the shape of the distribution. This method relies on three assumptions: 1) That the data is randomly sampled, 2) that the samples are normally distributed (*i.e.*, a bell-shaped distribution), and 3) that the samples are independent (*i.e.*, the sampling locations do not share common characteristics and are not clustered). The maps in Exhibit 14 clearly demonstrate that the study samples were not randomly collected across each state but were primarily in the southern and eastern portions of the states, even though carbofuran use is not restricted to those portions of the states. For example, Figure 1 in Exhibit 14 clearly shows that the vast majority of the wells sampled in North Dakota and South Dakota are in the eastern half of the state, and in Nebraska in the southern and eastern parts. Therefore the wells sampled will not be representative of the full distribution of wells in the state. On the second assumption, the analysis provided by the Petitioners did not determine whether the distribution was normal; the accuracy of percentiles at the tails of the distribution, such as the 95th percentile, are very sensitive to the accuracy of this assumption. Environmental data are usually not normally distributed; log-normal distribution is more typical (Ref. 60). If the shape of the distribution is not known, a non-parametric or 'empirical' estimation of the percentiles is better because it does not depend on the same assumption of normal distribution. Finally, the pH in various wells may or may not be statistically independent. Samples taken across the landscape are usually spatially correlated up to a certain distance. Beyond that distance, they are statistically independent. Unfortunately, this was not determined

as part of this analysis. While pH is clustered across the state, there is considerable spatial variability in pH conditions for both the subsurface and surface environments. This is especially true for shallow ground water systems, where local conditions can greatly affect the quality and characteristics of the water. This can be seen by comparing differences in pH values between counties within a state, and noting that even within a county individual wells will consistently yield ground water with either above- or below-average pH values for that county. Furthermore, even if the statistical calculations was correct, by definition this evidence would not support a determination that groundwater concentrations would never exceed 1.1 ppb, as 5 percent of the samples would result in concentrations that are higher.

In conducting its modeling for the final rule, EPA examined readily available data with respect to ground water and soil pH to evaluate the spatial variability of pH in Wisconsin. As part of the final rule, EPA explained that ground water pH values can span a wide range; this is especially true for shallow ground water systems, where local conditions can greatly affect the quality and characteristics of the water (higher or lower pHs compared to average values). As noted even within counties in the same state, wells will consistently yield ground water with either above- or below-average pH values for that county. Thus, EPA concluded that average ground water pH values for a given area do not truly characterize the (temporal and especially spatial) heterogeneity common in most areas. The actual significance of using a single pH even if it is a 95th percentile value, which as described above was not demonstrated to be accurately calculated, is

not clear. For this reason, EPA bracketed potential exposure using a range of pH values.

As further explained in the final rule, the considerable spatial variability in pH conditions for both the subsurface and surface environments is significant because the pH has a large effect on the persistence of carbofuran. This is demonstrated by the results of the ground water modeling simulations from the South-Central Wisconsin scenario, which show that what might appear as relatively small variations in soil pH can have a significant impact on estimates of carbofuran in ground water. Under more acidic conditions, the hydrolysis half-life increases from 28 days at pH 7 to years or more at pHs less than 6. Further, the results of EPA's corn ground water simulations (bounded by the high and low pH values of the aquifer system underlying the scenario location) showed that a relatively small (0.5) decrease in pH from 7 to 6.5 resulted in an increase by 4 orders of magnitude in the 1-in-10-year peak concentration of carbofuran.

The ground water simulations reflect variability in pH by modeling carbofuran leaching in four different pH conditions (pH 5.25, 6.5, 7.0, and 8.7), representing the range in the Wisconsin aquifer system. The upper and lower bound of pH values that EPA chose for this assessment were measured values from the aquifer, and the remaining two values were chosen to reflect common pH values between the measured values. Estimated 1-in-10-year peak ground water concentrations at pH 7 are $1.6 \times 10^{-3}$ ppb; however, the estimated 1-in-10-year peak ground water concentration at pH 6.5 is 16 ppb, nearly 4 orders of magnitude greater. EPA explained that, because of

carbofuran's sensitivity to pH, the Agency had concerns that any given set of mitigation measures would not successfully protect groundwater source drinking. Data indicate that pH varies across an agricultural field, and also with depth (Ref. 49). In particular, the pH can be different in groundwater than in the overlying soil. The upper bound of the carbofuran concentrations estimated by EPA at pH 6.5 is much greater than the concentrations the Petitioners reported in their objections. EPA's complete assessment of the 2008 revised label can be found in its Response to Comments document and these issues were addressed in more detail there (Ref. 84).

For all of these reasons, the objection is therefore denied.

*c. Objection/hearing request subissue: Consistency with groundwater concentration in NMC-CRA.* Petitioners object that EPA's estimates in the final rule are inconsistent with the groundwater concentration estimates EPA developed for the NMC (CRA). However, they do not identify any specific inconsistency, they simply make the general allegation. They allege that, by contrast, their assessment, which estimated maximum concentrations of 1.1 ppb, is consistent with the NMC CRA.

*i. Background.* The NMC CRA examined carbofuran at two sites, northeastern Florida and the Delmarva Peninsula. In Florida, concentrations were found to be below levels of concern because of high pH, but in Delmarva, both in corn and in melon scenarios EPA estimated that 90% of daily concentrations could be as high as 20.5 and 25.6 ppb, respectively. In the proposed and final rules, EPA cited the modeling conducted for the NMC to support its estimates. In

addition, EPA used the same methodology used to develop the estimates for the NMC CRA, to conduct the modeling for the additional crops and locations on which carbofuran use occurs.

Although the Petitioners alleged that their estimates were consistent with the NMC CRA in their comments on the proposed rule, they did not identify any specific inconsistency between EPA's groundwater estimates for the proposed rule and its estimates for the NMC CRA.

*ii. Denial of hearing request.* EPA denies the request for a hearing on this subissue because there is no disputed factual matter for resolution. There is no dispute as to the methodology EPA used to conduct its modeling in either assessment. Petitioners have not identified any specific inconsistency between EPA's groundwater exposure assessment conducted for this rule and the assessment conducted for the NMC CRA. Instead, they rely on mere allegations and denials. As EPA's regulations make clear, a mere "denial" of an EPA position is not sufficient to satisfy the standard for granting a hearing (40 CFR 178.32(b)(2)). Moreover the question of whether EPA's assessments are consistent requires the application of a legal standard to undisputed facts, and is thus a legal or policy question. Hearings are not appropriate on questions of law or policy (40 CFR 178.32(b)(1)). (73 FR 42696-42697) (denying a hearing on EPA's decision to reduce the children's safety factor, in the absence of data from the endocrine screening program, on the ground that the objection constituted a legal issue). FDA has repeatedly confirmed that the application of a legal standard to undisputed facts is a question of law for which a hearing is not required. (*See, e.g.*, 68 FR

46403, 46406 n.18, 46408, 46409 (August 5, 2003) (whether facts in the record show there is a reasonable certainty of no harm is a question of law; whether a particular effect is a "harm" is a question of law)).

Neither does the claim that their modeling is consistent with the NMC CRA justify a hearing on this question. As EPA explained in the final rule, the values estimated in the modeling conducted for the NMC CRA are greater than the 1 ppb that FMC claims is the maximum expected 1-in-10-year peak concentration. A hearing is not warranted where the claim is clearly contradicted by the record (40 CFR 178.32(b)(2)). *See, e.g.*, 57 FR 6667 (February 27,1992) ("A hearing must be based on reliable evidence, not on mere allegations or on information that is inaccurate and contradicted by the record."); 49 FR 6672 (February 22, 1984) (hearing denied where claim was based on demonstrably false premise).

*iii. Denial of objection.* As discussed in the final rule and response to comments document, the Petitioners' results are not consistent with the estimates developed for the NMC CRA. The NMC CRA examined carbofuran at two sites, northeast Florida and the Delmarva Peninsula. In Florida, concentrations were found to be below levels of concern because of high pH, but in Delmarva, both in corn and in melon scenarios EPA estimated that 90% of daily concentrations could be as high as 20.5 and 25.6 ppb, respectively. These values are greater than the 1 ppb that Petitioners claim is the maximum expected 1-in-10-year peak concentration.

*2. Objections relating to surface water exposure estimates—a. Objection/hearing request subissue: Use of percent of the crop treated (PCT) in surface water*

*modeling.* The Petitioners object to the assumption in the surface water assessments in the final rule that 100% of the crops in a watershed will be treated with carbofuran. The Petitioners argue that actual carbofuran sales data on a county basis from 2002-present demonstrate that the current carbofuran PCT is less than 4.25%. Using this PCT, and taking into account the recently submitted "no application buffers," the Petitioners allege that the modeling in Exhibit 15 demonstrates that carbofuran concentrations in surface water will not exceed 1.1 ppb, "which is below the level of concern."

In support of this objection, the Petitioners reference county level sales data that were submitted to the Agency on November 7, 2008, after the close of the comment period. They also reference the use tracking system proposed in their recent registration amendments (Exhibit 2) and the modeling contained in Exhibit 15.

*i. Background.* To conduct an assessment of a pesticide's potential to contaminate surface water, EPA estimates the percentage of farmland in a watershed on which a particular crop is grown (*e.g*, corn); this is referred to as the percent cropped area (PCA). EPA then assumes that 100% of the cropped area is treated with the pesticide that is the subject of the assessment. In the proposed rule, EPA explained that the reason for its assumption that 100% of PCA in a watershed is treated is due to the large uncertainties in the actual PCT on a watershed-by-watershed basis. EPA developed an extensive discussion of the uncertainties in PCT and how they impact drinking water exposure assessment in its proposed rule (73 FR 44885 (July 31, 2008)), and in a background document

previously provided to the SAP considering the draft carbofuran NOIC (Ref. 45). The data are generally not available on the scale necessary to allow for reliable estimates of pesticide use in a watershed. Such data are generally available only on a statewide basis, and if such estimates are used to account for PCT, it will underestimate the risks for some drinking water facilities in the state, as these estimates represent only a state-wide average. In some cases this underestimate can be substantial, because usage may not be evenly distributed across the landscape; due to differences in factors like pest pressure, local consultant recommendations, and weather, it may be much higher in some areas. Further, temporal uncertainties can result in changes in use that might be driven by weather, changes in insect resistance over time, and changes in agronomic practices. To date, methods that account for this uncertainty, given the nature of the available data, have not been developed. EPA explained that as a consequence, the Agency could not accurately estimate a drinking-water watershed scale PCT that, when used in a quantitative risk assessment on a national or regional basis, standing alone, provides the necessary level of certainty to allow the Agency to confidently conclude that exposures will meet the FFDCA section 408 safety standard. EPA also described the results of a sensitivity analysis conducted using a low PCT estimate.

In their comments on the proposed rule, the Petitioners criticized the Agency for this assumption, arguing that because carbofuran is used on such a low percentage of crops nationally that it is unrealistic to assume that such a large percentage of any individual

watershed would be treated. To support their claims that the PCT would generally be below 4%, they referenced county-level "use" data, but failed to provide either the data or methodology on which they relied until after the close of the comment period.

In the final rule, EPA explained at length the reasons that the information provided during the comment was insufficient to allow the Agency to reliably estimate a lower PCT for carbofuran. EPA did not review the information submitted after the close of the comment period. However, based on the information that could be gleaned from the description in the comments, EPA explained that the data on which they relied did not appear to be "use" data, but sales data, and that both the data and methodology failed to support the claims made in the Petitioners' comments. The Agency also described the results of a sensitivity analysis conducted to determine the impact that PCT could have on the risk assessment, which demonstrated that even assuming that a low percentage of a watershed is treated with carbofuran, exposures will still be unsafe for infants.

*ii. Denial of Hearing Request.* To the extent Petitioners' objection is limited to EPA's refusal to use a 4% PCT in estimating drinking water concentrations, EPA has concluded that the objection does not warrant a hearing because the Petitioners' objection on this subissue is irrelevant, and therefore immaterial, with regard to EPA's final tolerance revocation. The Petitioners have not responded to EPA's explanation in the final rule of the reasons that the information and methodology on which they relied to estimate a 4% PCT was flawed. As discussed in the final rule, EPA had assumed that the data on which they were relying

was sales data, and so the resubmission of the information sent in after the close of the comment period only confirms that the Agency's analysis was correct; it does not rebut EPA's substantive concern that such information is insufficient to support the conclusions the Petitioners assert. In essence, the Petitioners ignored EPA's extensive analysis of this issue in the final rule and simply refiled their comments on the proposal as if EPA's determination in the final rule did not exist. The statute, however, requires that objections be filed on the final rule not the proposal. By ignoring EPA's final rule on this issue, Petitioners have failed to lodge a relevant objection. When an objector does not challenge EPA's conclusions in the final rule, but merely reiterates comments made on the proposed rule, without submitting some evidence that calls EPA final rule conclusions into question, the objector has not raised a live controversy as to an issue material to the final rule (*See* 73 FR 42698-42699 (July 23, 2008) (denying several NRDC hearing requests because the objections were based on EPA's preliminary DDVP risk assessment, rather than the revised risk assessment published with the final order); 53 FR 53176, 53191 (December 30, 1988) (where FDA responds to a comment in the final rule, repetition of the comment in objections does not present a live controversy unless the objector proffers some evidence calling FDA's conclusion into question)).

An additional flaw in this objection is that the proffered evidence is untimely and insufficient. Neither the proposed registration amendments nor the evidence submitted as part of this objection, including the modeling in Exhibit 15, was provided to the Agency during the comment period. The modeling in

Exhibit 15 was available, because it was summarized in Petitioners' comments; however the underlying modeling was withheld. Equally, there is no evident reason that the sales data could not have been submitted as part of the Petitioners' comments. Petitioners relied on this data to perform analyses completed in 2006-2007, for purposes of the January 2008 SAP review of the draft carbofuran NOIC, so the information was available long before their comments needed to be filed. Accordingly, as discussed in Unit VI.D, this information is not appropriately considered as a basis for justifying a hearing on its final rule. Moreover, as explained below, because no evidence was submitted in support of the newly proposed use tracking system, reliance on that proposal to support a low PCT constitutes nothing more than an allegation. This is not an adequate basis on which to grant a hearing (40 CFR 178.32(b)(2)). Finally, to the extent this objection relies on Petitioners' recently proposed risk mitigation measures, as discussed in Units VI.C and D, objections and hearing requests based on these new risk mitigation measures are not appropriately considered at this stage of the administrative process, and are denied as immaterial (40 CFR 178.32(b)(3)).

*iii. Denial of objection.* While the Agency typically uses PCT in developing estimates of pesticide residues in food, this is entirely different than developing estimates of the percent of a watershed that is treated for purposes of estimating drinking water exposures. Food is generally randomly distributed for sale across the nation without regard to where it is grown. This tends to even out any PCT variations that may arise on local levels. By contrast, the source of water

consumption (and consequently exposure) is localized, either in a private well or a community water system. The PCT in any watershed will therefore directly impact the residues to which people living in that watershed will be exposed.

For this reason, among others, for drinking water exposure estimation, the Agency assumes that 100% of the cropped area (or 100% PCT) is treated with the pesticide. EPA also makes this assumption due to the large uncertainties in the actual PCT on a watershed-by-watershed basis. EPA included an extensive discussion of the uncertainties in PCT and how they impact drinking water exposure assessment in its proposed rule (73 FR 44834) and in a background document provided to the SAP considering the draft carbofuran NOIC (Ref. 45). Because usage is often not evenly distributed across the landscape, due to differences in factors like pest pressure, local consultant recommendations and weather, it may be much higher in some areas. Further, temporal uncertainties can result in changes in use that might be driven by weather, changes in insect resistance over time, and changes in agronomic practices. To date, methods that account for this uncertainty, given the nature of the available data, have not been developed. Consequently, EPA cannot accurately estimate a drinking-water watershed scale PCT that, when used in a quantitative risk assessment on a national or regional basis, standing alone, provides the necessary level of certainty to allow the Agency to confidently conclude that exposures will meet the FFDCA section 408 safety standard.

In most cases, EPA agrees that it is unlikely that 100% of the crop will be treated with a single pesticide

in most watersheds, particularly in larger watersheds. However, for small watersheds, it is reasonable to assume that an extremely high percentage of the crops in the watershed may be treated.

Moreover, EPA has an obligation to evaluate all legally permitted use practices under the label, and to ensure that all such use meets the requisite statutory standards, not simply to base its decisions on the practices the majority might typically use. The September 2008 proposed label, submitted during the comment period, imposes no restriction on the application of carbofuran related to whether a particular percent of the watershed has been treated. Thus, even with the restrictions on FMC's September 2008 labels, it remains legally permissible for 100% of the watershed to be treated with carbofuran.

Nor is EPA aware of an enforceable mechanism to ensure that farmers applying pesticide to their individual fields will have the ability to indendently determine whether a particular percentage of the watershed has been treated. There are significant practical difficulties inherent in implementing such label directions, as they force individual growers to have continual knowledge of the variances of the behavior of other farmers across the entire watershed. While for small watersheds that involve only one or two farms it might be feasible for neighbors to independently coordinate applications with respect to adjacent fields, for larger watersheds or for smaller watersheds with multiple farms, the practical difficulties increase significantly. And as explained below in Unit VI.F.2.D, significant questions remain

regarding the efficacy of Petitioners' proposed use tracking system.

However, in the final rule, EPA conducted a sensitivity analysis to explore the impact of the PCT assumption on dietary risk using an assumed 10% PCT, a figure proposed previously by FMC (74 FR 23065-23066). The results of that analysis demonstrated that even at these low percentages, which may significantly underestimate exposures, particularly in small watersheds, carbofuran exposures from drinking water contribute significantly to children's dietary risks. EPA conducted a similar sensitivity analysis for the final rule, discussed below in Unit VI.F.3, which demonstrates that even assuming that a low percentage of a watershed is treated, exposures will still be unsafe for infants.

Since EPA's 2006 determination that carbofuran does not meet the safety standard, FMC has submitted three assessments that relied in part on what they refer to as "county-level usage data" (Refs. 29, 74, and 89). Based on the information provided with the objections, the original source of the "county-level usage data" is sales data, apparently collected at the distributor level. The Petitioners claim to have augmented these sales data in an unspecified manner, by incorporating information from the distributors, which was used to allocate carbofuran usage at the county level. In their comments on the proposed rule, the Petitioners provided maps representing county level and watershed-scale use estimates, but did not provide the actual usage estimates in any clearly understandable format.

The Petitioners did submit these sales data as part of their objections, but have provided only a limited

description of how these data were collected and no description of how they were actually analyzed or validated; what was characterized as "careful and proven techniques to capture this data" were not described. The method used to attribute carbofuran sales to counties was not described. Nor have they explained what is meant by negative usage estimates.

The Agency agrees that county-level use data would be useful in generating reasonable estimates of PCT that might be appropriately used in drinking water assessments. However, no usage data have been provided. Rather, the Petitioners only provided county-level use estimates for Illinois, although they have not submitted the analyses that presumably are the basis for the estimates. County-level estimates to support other risk assessments have not been submitted by the Petitioners. Further, the Petitioners have provided limited characterization of the source data, noting that these data were derived from FMC billings and "EDI data", but they did not provide either the billings or the EDI data, nor explain how they were collected.

There are two major problems in equating sales information with use information: (1) Mapping the point and time of sale to the point and time of use and (2) allocating the amount sold across the crops on which it can be used. The submission did not explain how either of these two problems was resolved.

The first problem is highlighted by the fact that for some county/crop/year combinations in the submitted tables, estimated usage is negative. Use of a pesticide clearly cannot be negative, but sales at a particular point and time can be negative because buyers can return unused product. The fact that some usage

estimates are negative suggests that buyers are returning carbofuran product purchased in an earlier time period or from another location. But if farmers are returning carbofuran purchased in a previous time period, any assessment must also account for the possibility that they also could use stocks purchased previously. Thus, use in a given year may be greater than sales in that year. Similarly, if farmers are returning carbofuran purchased in another location, it must be recognized that they could be using carbofuran purchased in another location. Thus, use in any given county or watershed could be greater than sales in that locality. That is, regardless of whether the issue is use over space, time, or both, the results are that usage will be underestimated in some localities. Further, zeroing out the negative values will not result in appropriate estimates; the negative usage estimates merely make the problem manifest. Even total sales at a point in time may underestimate actual use.

The second problem arises with the allocation of product sales across the crops on which it can be used. The data provided as part of the objections were aggregated for all crops, including crops on which use is no longer allowed, such as cotton or alfala; the data were not collected based on the individual crops. No explanation is provided to indicate how the Petitioners divided the quantity sold between the amount used on cotton, on alfalfa, and on all other crops. Since part of the purpose of the Petitioners' assessment is presumably to show that eliminating the use on the cancelled crops, such as alfalfa, will sufficiently reduce any risks, it is critical to know how they determined the amount used on alfalfa as opposed to other crops, and it is difficult to imagine how this could be done with

any accuracy. For example, one could assume that the chemical is used on equal proportion of all crops, but there is no basis for such an assumption. It might not matter if all EPA were interested in was the total amount used in an area, but this is not useful for purposes of assessing the risk on a smaller scale, such as in the present case.

The method the Petitioners used to generate use estimates from the sales data does not account for the uncertainties described above nor for the potential for use to be locally concentrated due to pest pressures. The method that is summarily described as having been used to allocate county-level usage estimates to watersheds appears to be similar to a method that has been used by others to calculate "best-estimate" county-level PCT (Ref. 73) to map nationwide pesticide usage. However, these methods are not appropriate for calculating PCTs for surface drinking water sources or watersheds that drain to community water systems, because they do not adequately account for the uncertainty in the data at the appropriate spatial scale. This methodology produces an estimate that is a measure of central tendency and, as such, roughly half the estimated values will underestimate the PCT. Furthermore, because pesticide use varies from year to year, and can in some cases be patchy, with high levels of use in small areas and little use in most areas, the underestimates of PCT can be substantial in small watersheds. As previously noted, methods for calculating PCT that account for these uncertainties have not been developed. Accordingly, EPA denies this objection.

*b. Objection/hearing request subissue: Results of FMC modeling.* The Petitioners claim that the prior

surface water assessments submitted to the Agency demonstrated that carbofuran concentrations in surface water were not expected to exceed 1.1 ppb. They claim that these studies provide further confirmation of the results of the new modeling conducted to support their objections, which also concluded that concentrations would be less than 1.1 ppb. In support of this objection, the Petitioners reference the previously submitted studies, along with the modeling provided in Exhibit 15. The modeling in Exhibit 15 appears to be the modeling that was originally summarized in their comments, but that the Petitioners withheld. The modeling was also supplemented to account for the newly proposed registration amendments submitted as part of the objections.

*i. Background.* In their comments, the Petitioners alleged that the results of their modeling showed that concentrations of carbofuran in surface water would not exceed 1.1 ppb. The comments referenced two surface water assessments that they had submitted to the Agency prior to the proposed tolerance revocation: a surface water assessment based on an Indiana Community Water System (CWS) (Refs. 89 and 90) and an assessment based on the Watershed Regressions for Pesticides (WARP) model. They also summarized additional surface water modeling that had been conducted to support their comments on the proposed rule, a Nationwide Community Water System Assessment (Ref. 57), but did not submit the actual modeling, or identify or describe in detail the model on which they relied.

In the final rule, EPA explained the flaws in all of the Petitioners' assessments that caused the Agency to

reject the studies' conclusions. For the two assessments that had actually been submitted to the Agency, EPA was able to definitively explain the flaws. With respect to the Nationwide CWS modeling that was summarized in their comments, EPA evaluated the modeling based on the information it was able to glean from the description provided in the comment discussion.

*ii. Denial of hearing request.* A hearing is denied on this subissue because EPA has concluded that Petitioners' objection on this issue is irrelevant, and therefore immaterial, with regard to EPA's final tolerance revocation regulation (40 CFR 178.32(b)(3)). In the final rule, and in other rulemaking documents, EPA provided a detailed explanation of the bases for its conclusions that the previously submitted assessments were invalid (74 FR 23062-23064 (May 15, 2009)). Petitioners have not challenged EPA's explanation, nor explained how the resubmission of the same studies addressed the substantive issues EPA raised. Because Petitioners ignored EPA's extensive analysis of this issue in the final rule, they have essentially refiled their comments on the proposal as if EPA's determination in the final rule did not exist. The statute, however, requires that objections be filed on the final rule, not on the proposal (21 U.S.C. 346a(g)(2)). By ignoring the EPA's final rule on this subissue, Petitioners have failed to lodge a relevant objection. Petitioners' resubmission of the exact same information does nothing to call EPA's conclusion into question, which is what is required to maintain their claim at this stage of the proceeding. When an objector does not challenge EPA conclusions in the final rule, but merely reiterates comments made on the proposed

rule without submitting some evidence that calls EPA final rule conclusions into question, the objector has not raised a live controversy as to an issue material to the final rule. (See 73 FR 42700-42701 (July 23, 2008) (hearing request denied where NRDC failed to challenge EPA's conclusion that challenged study is consistent with several other studies, but merely reiterated assertions from its original petition that the study is not representative); 53 FR 53176, 53191 (December 30, 1988) (where FDA responds to a comment in the final rule, repetition of the comment in objections does not present a live controversy unless the objector proffers some evidence calling FDA's conclusion into question)).

With respect to the modeling submitted in Exhibit 15, this evidence is untimely. The modeling submitted in Exhibit 15 appears to be a fuller description of Petitioners' National CWS Assessment, which was described but not provided as part of their comments on the proposed rule. The modeling also has been revised to account for the newly proposed risk mitigation measures. However, even with the greater detail provided, the information contained in Exhibit 15 still fails to address many of the deficiencies EPA identified in the final rule. For example, although some further detail has been provided of how the Petitioners modeled the vegetated buffer strip, the complete information EPA would need to assess the modeling was not provided; the material provided is insufficient to understand how the simulations were performed or how the simulations were parameterized. Nor have the Petitioners submitted the inputs used in modeling estimated concentration from spray drift. As discussed in Unit VI.D, because the modeling in Exhibit 15 was

not provided during the comment period, and to the extent that the detailed information EPA identified as lacking in the final rule has still not been provided, the evidence submitted in Exhibit 15 is not appropriately considered as a basis for justifying a hearing on its final rule. And in the absence of this evidence, this objection consists of mere allegations and general denials, which are inadequate to justify a hearing (40 CFR 178.32(b)(2)).

Further, to the extent that this objection relies on the "no application buffers," or the proposed use tracking system newly submitted as part of their objections to support the models' assumption of a low PCT, the hearing request is denied as irrelevant, and therefore immaterial, to EPA's determination in the May 15, 2009 final rule, for the reasons discussed in Unit VI.C. Petitioners are actually not objecting to the conclusions in EPA's final rule; rather, they are suggesting that EPA might reach a different result in a different factual scenario. Objections, however, must be directed "with particularity [at] the provisions of the regulation or order deemed objectionable" (21 U.S.C. 346a(g)(2). And, as explained below, because no evidence was submitted in support of the newly proposed use tracking system, reliance on that proposal to support a low PCT constitutes nothing more than an allegation. This is not an adequate basis on which to grant a hearing (40 CFR 178.32(b)(2)).

*iii. Denial of objection.* To the extent this objection relies on Petitioners' newly submitted registration amendments, the objection is denied as immaterial. EPA also denies the remaining objections because, based on its review of the submitted modeling, EPA has concluded all of the modeling has substantial flaws

that render the model results invalid. EPA has previously reviewed these assessments, and provided a detailed explanation of the reasons for the Agency's conclusions, most recently, in the final rule and the associated response to comments (74 FR 23060-23064, Ref. 84). EPA's reasoning is summarized briefly below.

*Indiana CWS Assessment*

EPA has previously reviewed the Indiana surface water assessment, and has provided comments on that submission (Ref. 45), many of which were reiterated at length in the final rule and response to comments documents (74 FR 23062-23064, Ref. 84). The Petitioners originally submitted this study to demonstrate that "EPA's standard index reservoir scenario overestimates surface water concentrations compared with expected concentrations in actual Indiana CWS where carbofuran is used." The Index Reservoir is designed to be used as a screen, and as such, represents watersheds more vulnerable than most of those that support a drinking water facility. It is thus protective of most drinking water on a national basis. That, however, does not mean that EPA believes this scenario overestimates concentrations for all drinking water reservoirs. EPA agrees that it is an appropriate refinement to simulate local and regional watersheds, and has in fact done so (Refs. 44, 46, 47, 48, and 84). However, for the reasons discussed below, EPA does not believe that the Petitioners' assessment demonstrates that carbofuran concentrations will not exceed 1.1 ppb in Indiana surface water sources of drinking water. Even accepting the Indiana surface water assessment at face value, the estimated 1-in-10-year peak concentrations at some facilities were as high as 6.88 µg/L, and these concentrations

substantially exceed the 1.1 ppb concentration the Petitioners now claim represent reasonable estimates.

The study also fails to support the Petitioners' other conclusions. The study was originally intended to demonstrate two points: (1) That the vulnerability of the Indiana CWS "brackets" the Index Reservoir, and (2) that the concentrations they estimated for these locations are significantly less than EPA estimates. Regarding the vulnerability of the CWS, the assessment describes their approach for modifying the parameters of the Index Reservoir scenario to represent 15 reservoir-based watersheds in Indiana cropped in corn. The study indicates the Petitioners have included data that, based on EPA's review of these submissions, are not available at the appropriate scale to determine all site-specific parameters. The Petitioners modified some of the parameters based on available data to represent more localized conditions that are more or less vulnerable than for the Index Reservoir. From the description, the Petitioners' approach is similar to the methods that EPA uses to develop new scenarios, in that soil and weather data are varied in order to represent different locations. However, for other parameters, EPA believes the modifications are inconsistent with fundamental assumptions upon which the modeling is based. In previous submissions to the Agency, FMC has described that they have made modifications to scenarios to reflect local conditions of each CWS in Indiana by modifying the soil and weather data and altering the ratio of watershed drainage area to the reservoir capacity (Ref. 89). EPA agrees that soil and weather data can be modified to reflect conditions at local watersheds. However, EPA disagrees that

altering the ratio of watershed drainage area to the reservoir capacity (*i.e.*, the DA/NC) is a reasonable modification.

The DA/NC parameter is associated with increased concentrations in drinking water reservoirs to a certain point. The Petitioners adjusted their EDWCs for each drinking water facility by a factor representing the ratio of the DA/NC for each reservoir divided by the DA/NC for the Index Reservoir (which is 12). EPA does not believe this is appropriate for two reasons. First, the relationship between concentrations and the DA/NC is not strictly linear. Small DA/NCs imply a small watershed combined with a large reservoir. As the DA/NC increases, the relative watershed size increases, and thus the runoff volume going into the reservoir also increases. This is also means the reservoir's ability to dilute the runoff decreases; the result is that concentrations increase with an increase in the DA/NC. However, at some point, the runoff volume exceeds the reservoir capacity, and rather than increasing the pesticide concentration, the excess runoff flows out of the reservoir, carrying the pesticide with it. Thus, because pesticide concentrations are not linearly related to the DA/NC, it is not appropriate to multiply the model output by a linear DA/NC adjustment factor. Secondly, the PRZM model, which is used to simulate the watershed for the Index Reservoir, is a field-scale model. As the watershed size (and the DA/NC) increases, assumptions upon which PRZM relies (namely: uniformity of soils, equal and simultaneous movement of runoff to the reservoir, and uniform weather across the watershed) no longer hold and the model becomes less valid for simulating the runoff processes. The geometry of the Index Reservoir

was chosen partly to avoid these two limitations (Ref. 43).

The study authors also calculated their own PCA values[19] for this assessment. EPA uses the maximum PCA calculated for any HUC8 (8-digit hydrologic unit code) watershed in exposure estimates. HUC8s are cataloging units for a watershed developed by the USGS and are used as surrogates for drinking water watersheds. The process by which PCAs were developed and how they are used by the Agency has been vetted with the FIFRA SAP (Refs. 30 and 31). The Agency has developed PCAs for four major crops—corn, soybeans, wheat, and cotton—and uses a default PCA based on all agricultural land for characterizing other crops. The Agency has also calculated regional default PCAs for use in characterizing regional differences in drinking water exposure. EPA limited further development of PCAs for additional crops in response to the FIFRA SAP peer review, which concluded that the data were not available at the appropriate scale to do so. The Petitioners' assessment estimated PCAs for specific watersheds in Indiana, but did not provide sufficient detail in their descriptions of how they calculated those PCAs to enable EPA to assess their validity.

Regarding the statement that the concentrations estimated for the study locations in Indiana are significantly less than EPA estimates, EPA has determined that the Petitioners included an adjustment factor to account for the percent of a crop that is treated with carbofuran. As previously

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[19] The PCA is the fraction of the drinking water watershed that is used to grow a particular crop.

discussed, EPA does not believe that it is appropriate to base its aggregate risk estimates on PCT within watersheds. This is because data and/or methods are not available that would allow EPA to develop PCT at the watershed scale with the necessary level of confidence to allow EPA to make a safety finding. The PCT factors that the Petitioners applied would generate significantly lower concentrations than those estimated by EPA.

*WARP Assessment*

EPA has reviewed the WARP assessment previously and has provided comments on the submission (Refs. 45 and 86). The WARP model has not been fully evaluated for quantitative use in exposure estimation by the Agency, although it has been preliminarily reviewed by the SAP (Ref. 32). EPA used WARP to select monitoring sites for the herbicide atrazine, based on predicted vulnerability of watersheds to atrazine runoff within the corn/sorghum growing regions. EPA presented its approach to the FIFRA SAP in December 2007. The SAP report concluded that "WARP appears to be a logical approach to identify the areas of high vulnerability to atrazine exposure," endorsing EPA's use of this tool only for atrazine, and for the limited purpose of designing a monitoring program. The SAP noted that the most important explanatory variable with WARP was use intensity, which underscores the importance of having the most accurate data for this parameter.

WARP is a regression model developed by the USGS to estimate concentrations of the pesticide atrazine in rivers and streams. As a regression model, it is based on monitoring data from 112 USGS NAWQA monitoring locations. WARP does not directly

estimate daily concentrations, but predicts the percent of the time in a randomly selected year that concentrations of the pesticide are less than a specified value, with a specified level of confidence. USGS attempted to develop an approach to estimate annual time series for other pesticides, and concluded that "further data collection and model development may be necessary to determine whether the model should be used for areas for which fewer historical data are available * * * Because of the relative simplicity of the time-series model and because of the inherent noise and unpredictability of pesticide concentrations, many limitations of the model need to be considered before the model can be used to assess long-term pesticide exposure risks" (Ref. 92).

The Petitioners had previously relied on their WARP assessment to support the conclusion that the "maximum 1-in-10-day estimated concentrations of carbofuran at the 90th percentile level in Illinois, Indiana, Iowa, and Nebraska * * * will be less than or equal to 0.3687 ppb." This is erroneous. WARP does not provide direct estimates of return frequency, *i.e.*, 1-in-10 days, but rather percentiles of the expected distribution of measurements. This may be similar but not identical to the return frequency expressed as a percentile, depending on the number of measurements used to support the regression. EPA lacked the information necessary to determine whether the contractor calibrated the model correctly. However, taking the conclusion at face value, the value the Petitioners predicted using WARP, 0.3687 ppb, appears to represent the maximum of the estimated values of the annual 90th percentile among all the sites evaluated. Such a site would be expected to have

higher concentrations than 0.3687 ppb about 37 days a year (10% of the year). Generally, the 90% prediction intervals tend to be about plus or minus an order of magnitude. Thus, roughly 5% of such sites could have about 37 days a year greater than about 3.7 ppb, or over 3-fold higher than the 1.1.ppb concentrations the Petitioners now claim will be the maximum concentrations in surface water.

The Agency also disagrees that the differences between the Petitioners' and EPA estimates are only due to Petitioners' use of county-level use estimates. Most importantly, the Petitioners relied on estimates of 1-in-10-day concentrations, rather than the 1-in-10-year peak concentrations estimates used routinely by EPA. 1-in-10-day concentrations are not the measurement endpoint EPA uses for human health risk assessment and are not appropriate for estimating drinking water exposure. The Agency uses 1-in-10-year peak concentrations for screening level assessments, and the full time series (typically 30 years) of daily concentration values for refined assessments. EPA's reliance on the 1-in-10-year peak concentration has been reviewed and approved by the FIFRA SAP (Ref. 30).

A concentration that occurs 1-in-10 days occurs 350 times as often as a 1-in-10-year event. Using this value instead of the one EPA used would result in significantly lower estimates of pesticide water concentration and human exposure. For example, EPA's estimate of the 1-in-10-year peak concentration from the simulation of corn in Kansas with a 300 ft buffer was 31.8 ppb. By contrast, EPA's estimate of the 1-in-10-day concentration from the same simulation was 4.5. Use of the 1-in-10 day concentration to assess

dietary risk would be inconsistent with the SAP's advice and EPA's typical practice, as well as with EPA's statutory requirement to protect human health.

EPA disagrees with the Petitioners' claim that "the extreme nature of a 1-in-10-year event would result in dilution effects that cancel out any increased loading." The Index Reservoir scenario has been validated against monitoring collected at the site it was designed to represent, Shipman City Lake in Illinois (Ref. 43). This assessment showed that the 1-in-10-year event EPA modeled was similar in magnitude to the peak value of the pesticide concentrations shown in 5 years of monitoring data collected at that site. The 1-in-10-year peak concentration calculated for that pesticide (not carbofuran), using the Index Reservoir was 33 ppb, while the peak value from 5 years of monitoring was 34 ppb.

EPA cannot determine the validity of the use intensities assumed for the Petitioners' assessment. The source of county level use data appears to have been sales data at the distributor level, similar to the data provided in the Petitioners' November 7, 2008 submission. However, as previously explained, the method chosen to estimate county level use estimates from the sales data was not provided. The county level estimates used in the assessment for 2002 to 2004 for Illinois were provided in a table. These estimates for each county were averaged over the 3 years for input to the model. A summary description of how watershed-scale use estimated from county level use data was provided, but because the sales data for the individual crops and the method that was used to generate county level estimates were not available, the validity of this assessment cannot be evaluated.

*Nationwide CWS Assessment*

EPA has previously reviewed the Petitioners' "Nationwide CWS Assessment" and provided a response to the submission as part of the final rule and Response to comments (Ref. 45). As a preliminary matter, this assessment only included use intensity for reservoir-based systems, and excluded use intensity for all stream- or river-based systems from their assessment. Therefore, this assessment provides no evidence to demonstrate that carbofuran can be safely used in stream or river-based community water systems.

Similar to the Indiana CWS study discussed above, this study relied on county-level usage estimates to estimate use intensity. The National CWS Assessment concluded that a use intensity below 2.1 lbs a.i/mi$^2$ would assure that surface water concentrations will be below the level of concern.

To evaluate the study, it is therefore important to understand how the use intensities were derived. The Petitioners' methods have been poorly described, but EPA has been able to piece together a general sense of the methods from the various reports provided to EPA. To summarize, the Petitioners relied on sales data to generate the use intensity estimates, but the method used to generate the county-level use estimates from the sales data is not described. The actual county level use estimates used in the use intensity calculations were not provided. There is a limited description indicating only that the county level use estimates were apportioned to different crops, but the method used to do this was not provided. The Petitioners appear to have used an objective method to group the county-level use estimates into 5 classes, but

the method is only briefly described. Thus, because EPA cannot determine how use intensity was estimated, the Agency cannot determine if the conclusions made in the National CWS Assessment are justified by the underlying data.

In the absence of this information, EPA is unable to substantiate the study conclusion that 75% of the permissible use areas have a carbofuran use intensity below 2.1 lbs a.i/mi$^2$—even assuming that reliance on only 75% of the use areas would be protective, and nothing has been submitted to substantiate that conclusion. Use intensity maps that were provided with the Petitioners' comments appear to indicate that carbofuran use varies year by year, and it is not clear for which year or years, the Petitioners are relying to support their claim that use intensity will be below 2.1 lbs a.i/mi$^2$. No further support for this claim was provided with the Petitioners' objections, even though EPA presented its conclusions in the final rule.

As noted, the National CWS Assessment assumed that a use intensity below 2.1 lbs a.i/mi[FN2] would assure that surface water concentrations will be below the level of concern. EPA agrees that using lower rates of carbofuran will result in lower exposure. But EPA does not agree that it has been demonstrated that a use intensity below 2.1 lbs a.i./mi$^2$ will assure that surface water concentrations will be below the applicable level of concern. The National CWS Assessment does not justify such a finding, nor has any other assessment that has been submitted to date. The Agency modeled use rates for carbofuran on corn based on the label proposed in September 2008, which are the rates at which farmers are legally allowed to apply carbofuran, and the results clearly demonstrate that

estimated exposures will substantially exceed safe levels. The results of EPA's assessments are described in more detail in Unit V.E. of this order, the final rule and in Reference 111.

EPA is equally unable to confirm the study's claim that the no-application buffers on the September 2008 labels will adequately mitigate the risks "in areas with historical use intensities greater than 2.1 lbs a.i./sq. mi." On the September 2008 labels, FMC included buffers of 300 feet on water bodies in Kansas, and 66 feet around water bodies in other places, but EPA cannot evaluate how these buffers relate to areas where carbofuran use intensities exceeded a specific value, for all of the reasons stated above. EPA did, however, model the effects from the buffers proposed on the September 2008 labels and found that these buffers reduce exposure by 5.1% (33.5 to 31.8 ppb) for corn in Kansas with a 300-foot spray drift buffer and 4.7% (29.9 to 28.5 ppb) for corn in Texas with a 66-foot spray drift buffer. However, even with the buffers, EPA's analyses clearly demonstrate that estimated exposures will substantially exceed safe levels. These results are described in more detail in Unit V.E. of this order, the final rule, and Reference 84, Appendix I. For all of these reasons, the objection is denied.

*c. Objection/hearing request subissue: Challenges to EPA use of NAWQA monitoring data.* The Petitioners object to EPA's discussion in the final rule of the extremely high concentrations detected in Zollner Creek in Oregon. They argue that reliance on these concentrations to confirm the results of EPA's modeling is not supportable because Zollner Creek is a small isolated creek, not a drinking water source, and that because of its size, is not representative of

potential drinking water anywhere else. They also argue that the majority of the concentrations in the NAWQA data, including those detected at Zollner Creek, are extremely low-below the 1.1 ppb they claim is supported by their modeling. They also contend that the higher observed concentrations in the NAWQA monitoring data are the result of use patterns that are no longer permitted, and that allowed a much higher use rate than is currently permitted.

*i. Background.* In the proposed rule, EPA described the available monitoring data that characterized carbofuran concentrations in surface water. EPA described that the highest concentrations of carbofuran are reported from a sampling station on Zollner Creek, which EPA acknowledged "is not directly used as a drinking water source" (73 FR 44883). USGS monitoring at Zollner Creek from 1993 to 2006 detected carbofuran annually in 40–100% of the samples. EPA stated that although the majority of the concentrations detected were in the sub-part per billion range, concentrations have exceeded 1 ppb in 8 of the 14 years of sampling (Id.). The maximum measured concentration was 32.2 ppb, observed in the spring of 2002. EPA compared its modeling results to the concentrations seen in all of the USGS monitoring, Safe Drinking Water Act (SDWA) monitoring, and to the results of the available field scale studies. EPA concluded that the concentrations estimated in its modeling were consistent with the results of all of the available monitoring and studies (73 FR 44883-44884).

In their comments on the proposed rule, the Petitioners alleged that comparisons between EPA's modeling concentrations and Zollner Creek detections were inappropriate because they were based on "older

data [that] are not reflective of future carbofuran use areas and/or intensities" (Ref. 18 at 55). In support, they claimed that "carbofuran was once used at several nurseries and strawberry farms in the Zollner Creek watershed at estimated application rates of up to 15 lbs. a.i./acre (5 times higher than the maximum rate on the current label, and 15 times higher than the most common use rates)" (Id at 56).

In the final rule, EPA explained that it had not relied solely on Zollner Creek concentrations to validate its modeling. EPA again described the results of all available modeling, which included the detections at Zollner Creek, but also included results from all other NAWQA sites, SDWA post-treatment monitoring, and the results of field studies. Based on all of these data, EPA concluded that the results of the revised modeling conducted for the final rule was consistent with the available monitoring data.

*ii. Denial of hearing request.* This subissue does not meet the standard for a hearing. The objections regarding Zollner Creek are not material. EPA did not rely in on the concentrations detected at Zollner Creek to provide significant support its assessment.

In the final rule, EPA was clear that it considered the levels seen at Zollner Creek to be a rare circumstance:

> While available monitoring from other portions of the country suggests that the circumstances giving rise to high concentrations of carbofuran may be rare, overall, the national monitoring data indicate that EPA cannot dismiss the possibility of detectable carbofuran concentrations in some surface waters under specific use and environmental conditions.

(74 FR 23081). The final rule was clear that EPA placed greater reliance on the concentrations detected in Safe Drinking Water Act (SDWA) post-treatment monitoring, showing concentrations ranging between 4 and 7 ppb (74 FR 23079-23080). EPA also discussed the results of the UK tile drain studies as supplemental confirmation of its modeling (74 FR 23082).

Petitioners' contentions regarding the NAWQA monitoring also fail to present a genuinely-disputed issue of material fact. In both the proposed and final rules, EPA acknowledged the large percentage of non-detections and low concentration levels in the majority of the NAWQA monitoring data, and repeatedly explained the reasons that these data cannot serve as lower or upper bounds (73 FR 44882-44883; 74 FR 23081). Petitioners do not dispute those conclusions, or submit evidence to rebut them. When an objector does not challenge EPA conclusions in the final rule, but merely reiterates comments made on the proposed rule, without submitting some evidence that calls EPA final rule conclusions into question, the objector has not raised a live controversy as to an issue material to the final rule. (See 73 FR 42700-42701 (denying hearing request where NRDC failed to object to the basis EPA asserted in its petition denial for rejecting their original challenge). Finally, no evidence has been submitted to support the contention that all of the higher concentrations exclusively result from uses or higher use rates that are no longer permitted. Hearings will not be granted on mere allegations (40 CFR 178.32(b)(2)).

*iii. Denial of objection.* Data compiled in 2002 by EPA's Office of Water show that carbofuran was detected in treated drinking water at a few locations. Based on samples collected from 12,531 ground water

and 1,394 surface water source drinking water supplies in 16 states, carbofuran was found at no public drinking water supply systems at concentrations exceeding 40 ppb (the MCL). Carbofuran was found at one public ground water system at a concentration of greater than 7 ppb and in two ground water systems and one surface water public water system at concentrations greater than 4 ppb (measurements below this limit were not reported). Sampling is costly and is conducted typically four times a year or less at any single drinking water facility. The overall likelihood of collecting samples that capture peak exposure events is, therefore, low. For chemicals with acute risks of concern, such as carbofuran, higher concentrations and resulting risk is primarily associated with these peak events, which are not likely to be captured in monitoring unless the sampling rate is very high.

Unlike drinking water derived from private ground water wells, drinking water from public water supplies (surface water or ground water source) will generally be treated before it is distributed to consumers. An evaluation of laboratory and field monitoring data indicate that carbofuran may be effectively removed (60-100%) from drinking water by lime softening and activated carbon; other treatment processes are less effective in removing carbofuran (Ref. 81). The detections between 4 and 7 ppb, reported above, represent concentrations in samples collected post-treatment. As such, these levels are of particular concern to the Agency. An infant who consumes a single 8-ounce serving of water with a concentration of 4 ppb, as detected in the monitoring, would receive approximately 130% of the aPAD from water consumption alone.

To further characterize carbofuran concentrations in surface water (e.g., streams or rivers) that may drain into drinking water reservoirs, EPA analyzed the extensive source of national water monitoring data for pesticides, the USGS NAWQA program. The NAWQA program focuses on ambient water rather than on drinking water sources, is not specifically targeted to the high use area of any specific pesticide, and is sampled at a frequency (generally weekly or bi-weekly during the use season) insufficient to provide reliable estimates of peak pesticide concentrations in surface water. For example, significant fractions of the data may not be relevant to assessing exposure from carbofuran use, as there may be no use in the basin above the monitoring site. Unless ancillary usage data are available to determine the amount and timing of the pesticide applied, it is difficult to determine whether non-detections of carbofuran were due to a low tendency to move to water or from a lack of use in the basin. The program, rather, provides a good understanding on a national level of the occurrence of pesticides in flowing water bodies that can be useful for screening assessments of potential drinking water sources.

The national monitoring data indicate that EPA cannot dismiss the possibility of detectable carbofuran concentrations in some surface waters under specific use and environmental conditions. Even given the limited utility of the available monitoring data, there have been relatively recent measured concentrations of carbofuran in surface water systems at levels above 4 ppb and levels of approximately 1 to 10 ppb measured in streams representative of those in watersheds that support drinking water systems (Ref. 81). Based on

this analysis, and since monitoring programs have not been sampling at a frequency sufficient to detect daily-peak concentrations that are needed to assess carbofuran's acute risk, the available monitoring data, in and of themselves, are not sufficient to establish that the risks posed by carbofuran in surface drinking water are below thresholds of concern. Nor can the non-detections in the monitoring data be reasonably used to establish a lower bound of potential carbofuran risk through this route of exposure. Nevertheless, these results are consistent with the results of EPA's surface water modeling (Refs. 12, 47, 67). For all of these reasons, the Petitioners objection is denied.

*d. Objection/hearing request subissue: New label restrictions and revised terms of registration.* As discussed in Units VI.C and D, FMC submitted a request to amend its existing registration to incorporate a requirement intended to ensure that no more than 2% of any watershed will be treated with carbofuran. Petitioners allege that these new use restrictions will ensure that drinking water concentrations will not exceed 1.1 ppb. In support, the objection presents a June 30, 2009 letter describing the restrictions, along with proposed revisions to the carbofuran labels.

*i. Background.* On June 30, FMC requested that EPA amend its registration to incorporate a requirement that, within five days of applying the product, all applicators report to FMC the following information: the location that the product will be used; crop, use rate, application method, acreage, and quantity applied. Based on this information, FMC would track the percentage in each watershed. "Whenever it appears that carbofuran has been applied

to 1.75% of any watershed," the registrant would report that information immediately to EPA, "cease further sales in any county that overlaps with such a watershed for that use season, and shall attempt to recall all unused carbofuran within such counties by offering to repurchase such unused product" (Exhibit 3). In addition, FMC requested that its registration be amended to require that "based on watershed boundaries, FMC * * * prior to each uses season, allocate to its distributors in a manner which will attempt to ensure that no distributor receives more for carbofuran for sale than can be accommodated by the 2% watershed area cap in any watershed supplied by that distributor."

*ii. Denial of hearing request.* EPA denies this hearing request on two grounds. First, discussed in VI.C, Petitioners' objections and hearing requests are denied as irrelevant, and therefore immaterial, to EPA's determination in the May 15, 2009 final rule that the carbofuran tolerances were unsafe and could not be sustained under FFDCA section 408. Petitioners are actually not objecting to the conclusions in EPA's final rule; rather, they are suggesting that EPA might reach a different result in a different factual scenario. Objections, however, must be directed "with particularity [at] the provisions of the regulation or order deemed objectionable" (21 U.S.C. 346a(g)(2)). Further, as discussed in Unit VI.D, this objection is untimely, because it was not raised in comments. Neither this specific proposal, nor any other proposal regarding a potential tracking system, was presented to EPA by the close of the September 29, 2008 comment period. EPA therefore considers this issue

waived, and will not consider this as an appropriate basis for justifying a hearing on its final rule.

However, there is a further equally material defect in this hearing request. The Petitioners have submitted no evidence to support their allegation that these proposed requirements would be effective in ensuring that carbofuran would be applied to no more than 2% of any watershed. The only submission was the description provided in the June 30 letter (Exhibit 3), and repeated above. However, this vague description leaves several critical questions unanswered. For example, the critical component of this proposal is a post-use reporting scheme, with a five-day delay between use and reporting. Even assuming that one accepts that reporting an address would allow for complete identification of the location within an individual watershed—a point on which no evidence has been submitted—no evidence, or even an explanation, has been provided to demonstrate how this after-the-fact reporting requirement will prevent application to greater percentages of the watershed. For smaller watersheds, as discussed in the final rule, application to only one or two farms may be sufficient to substantially exceed 2% of the watershed. In such cases, since applicators are only required to report within five days after application, it is likely that FMC would not be informed until after the 2% cap had been exceeded. Further, there will inevitably be some delay between FMC's attempt to repurchase the product and the reports suggesting (or confirming) that the cap either has been or will shortly be exceeded. Given the inevitable delay, it is not unlikely that further application would occur before FMC could even attempt to repurchase the product. No details

whatsoever have been provided regarding the timing or mechanism by which this would occur. Further, this program operates in the absence of any enforceable use restriction, and no description of the means by which this would be enforced is provided. Although the company would "attempt to recall the product" or make it less available by "attempting" to direct sales to particular distributorships, in the absence of some mechanism to prevent sales or use, such as a permitting process, there is no real assurance that these voluntary measures would be effective (Exhibit 3). This is further complicated by the extremely low percentages contemplated by this proposal.

Additionally, this scheme rests on a variety of assumptions that no evidence has been submitted to substantiate. For example, the proposal to restrict sales to distributors in particular watersheds rests on an assumption that farmers always purchase products from a distributor within their watershed. It also assumes that growers and distributors will accept FMC's offer to repurchase unused stock of the products, rather than seeking to stockpile the product for use in the next growing season.

In the absence of any evidence to demonstrate the efficacy of these proposed restrictions, any objection based on these proposed amendments constitute no more than mere allegations or denials. Hearings will not be granted on such a basis (40 CFR 178.32(b)(2)).

*iii. Denial of objection.* For the reasons discussed above, even if it were appropriate to consider the proposed registration amendments, EPA is unable to conclude that those amendments would ensure that concentrations of carbofuran in drinking water derived

from surface water will not exceed 1.1 ppb. Accordingly, the objection is denied.

*e. Objection/hearing request subissue: Consistency with NMC surface water estimates.* Petitioners object to EPA's surface water exposure estimates on the ground that they are inconsistent with the estimates EPA developed for purposes of the NMC CRA. Petitioners further claim that their revised surface water assessment is consistent with the EPA estimates in the NMC cumulative risk assessment. The evidence proffered for this objection consists of the modeling in Exhibit 15.

*i. Background.* In comments on the proposed rule, the Petitioners complained that as part of the NMC CRA, EPA relied on actual "county-or multi-county level pesticide use information, based on agricultural chemical use surveys" to develop its estimates of potential exposure, rather than assuming 100% PCT." In the final rule, EPA provided a lengthy and detailed explanation of the reasons that its approach to assessing individual chemicals and its approach to assessing the cumulative risks of multiple chemicals differed (74 FR 23067-23068 (May 15, 2009)).

*ii. Denial of hearing request.* To the extent Petitioners base this objection on the concerns raised in their comments, EPA denies the hearing request on this subissue because there is no disputed factual matter for resolution at a hearing. There is no dispute that EPA assumed 100% PCT for carbofuran in its surface water modeling, nor that EPA developed lower estimates in the NMC CRA, that accounted for the percent of the crop that was likely to be treated with each individual NMC chemical in order to more accurately account for the likelihood of pesticide co-

occurrence at a single drinking water facility. Thus, the only question is whether EPA's basis for adopting a different approach between the assessment of a single chemical's aggregate exposure and the assessment of the cumulative exposures from several chemicals is reasonable. This question requires the application of a legal standard to undisputed facts. Hearings are not appropriate on questions of law or policy (40 CFR 178.32(b)(1)); (73 FR 42706-42707 (July 23, 2008)). FDA has repeatedly confirmed that the application of a legal standard to undisputed facts is a question of law for which a hearing is not required. (*See, e.g.*, 68 FR 46403, 46406 n.18, 46408, 46409 (August 5, 2003) (whether facts in the record show there is a reasonable certainty of no harm is a question of law; whether a particular effect is a "harm" is a question of law)).

In addition, Petitioners have not challenged the substance of EPA's response to their comments or submitted evidence that calls the substance of EPA's conclusions into question (40 CFR 178.32(b)(3)). Consequently, the Petitioners' objection on this issue is irrelevant, and therefore immaterial, with regard to EPA's final tolerance revocation regulation because Petitioners ignored EPA's extensive analysis of this issue in the final rule and essentially resubmitted their comments on the proposal as if EPA's determination in the final rule did not exist. The statute, however, requires that objections be filed on the final rule, not on the proposal (21 U.S.C. 346a(g)(2)). By ignoring the EPA's final rule on this subissue, Petitioners have failed to lodge a relevant objection. Both EPA and FDA precedent make clear that when the agency substantively responds to comments on the proposal, the commenter may only keep that issue alive in its

objections by addressing the agency's substantive response. *See* 73 FR 42698-42699 (When an objector does not challenge EPA conclusions in the section 408(d)(4)(iii) order but rather challenges some prior conclusion that was superseded by the section 408(d)(4)(iii) order, the objector has not raised a live controversy as to an issue material to the section 408(d)(4)(iii) order; 53 FR 53176, 53191 (December 30, 1988) (where FDA responds to a comment in the final rule, repetition of the comment in objections does not present a live controversy unless the objector proffers some evidence calling FDA's conclusion into question)).

To the extent this objection is simply an allegation that the results of the modeling are consistent with the surface water estimates in EPA's NMC risk assessment, the hearing request also suffers from a fatal flaw. The modeling is based on the assumption the recently proposed label restrictions are effective, and that the PCT will be 2%. Because the objection and hearing request are inextricably intertwined with the Petitioners' newly submitted proposed FIFRA registration amendments, the objection and hearing request are denied as irrelevant, as discussed in Unit VI.C. Further, as discussed, no evidence was submitted to support the assumption that the newly submitted use tracking proposal will be effective. The only evidence submitted in this regard is the results of the modeling in Exhibit 15, which as previously discussed is untimely, and therfore provides an inappropriate basis for a hearing. This evidence, therefore, on multiple grounds is insufficient to support a reasonable possibility that the issue will be resolved

in the Petitioners' favor. No hearing is warranted under such circumstances (40 CFR 178.32(b)(2)).

*iii. Denial of objection.* While it is true that in the NMC assessment EPA used PCT numbers to estimate the cumulative exposure from the contamination of such pesticides in surface water, this was done in order to more accurately account for the likelihood of pesticide co-occurrence at a single drinking water facility. But this does not mean that use of PCT is appropriate in conducting an assessment of aggregate exposure from carbofuran residues in surface water. This difference in approach between the assessment of a single chemical's aggregate exposure, and the assessment of the cumulative exposures from several chemicals, stems from the differences in the purpose and scope of the two assessments. These differences inevitably require the application of different methodologies.

In evaluating the acute risks associated with a single chemical's contamination of drinking water, EPA must consider all of the variations permitted under the label. Drinking water exposures are driven by uniquely local factors; not only is the source of drinking water local (*i.e.*, a person drinks water from his or her local water system, not from a combination of water systems from across the United States), but the likelihood and degree of contamination of any particular, local drinking water source, whether it is a reservoir or well, varies widely based on local conditions (*e.g*, from local pest pressures, weather). Given this local variability, EPA must evaluate how all of the practices permitted under the label will affect drinking water exposures, because all are legally allowed, and farmers may choose any of them based on

their particular individual local conditions. This means that even if growers, on a national or regional basis, do not frequently use a particular practice, EPA must still evaluate whether aggregate exposures from that practice would be safe because the practice is legally permissible and may be used due to local conditions. Thus, for example, even if most growers tend to apply the chemical only to a portion of the field, or typically only apply one-half of the maximum application rate, EPA must determine whether use by all or some growers on the entire field or at the maximum rate in a local watershed would result in unsafe drinking water concentrations.

By contrast, it is not feasible to conduct the identical analysis for a cumulative assessment of related chemicals. Since the potential combinations of variations in pesticide use practices for the group of pesticides to be assessed are essentially infinite, even with computer modeling it would be impossible to model or evaluate all of the combinations allowed under the labels. EPA therefore needed to narrow its evaluation of the possible combinations to those deemed "likely" to occur. In contrast to the single chemical assessment, a cumulative assessment is intended to develop a snapshot in time of what is likely occurring at the moment. Moreover, the purpose of a cumulative assessment is to identify major sources of risk that could potentially accrue due to the concurrent use of several pesticides that act through a common mechanism of toxicity. Thus, EPA is primarily interested in the subset of circumstances in which residues from such pesticides occur concurrently (or co-occur).

In addition, one of the important attributes of a cumulative risk assessment is that its scope and complexity can potentially lead to inflated estimates of risk due to compounding conservatisms, which would reduce the interpretability and ultimately the utility of the assessments. Because many data sets need to be combined, reducing the impact and likelihood of compounding conservative assumptions and over-estimation bias becomes very important in constructing a reasonable cumulative risk assessment.

When little or no information is available to inform potential sources of exposure, such as a reasonable or maximum watershed scale PCT, it is both scientifically and legally reasonable for a single chemical assessment to incorporate conservative assumptions to reflect reasonable worst-case exposure estimates. But in a cumulative risk assessment, the incorporation of such conservative assumptions would imply multiple simultaneous reasonable worst-case exposure estimates for each individual chemical. This is so unlikely that the results would no longer represent even a reasonable worst-case estimate of the likely risks. Consequently, some of the conservative assumptions appropriately used in the single chemical risk assessments are not appropriate or reasonable for use in a cumulative risk assessment, and vice versa.

As a result, EPA chose in the NMC to work with those data that most closely reflect "representative" exposures, and developed "representative" estimates of PCT in regional watersheds. However, to be clear, the PCT values used in the NMC assessment do not represent estimates of 50% of watersheds, or even the "average" watershed; rather, they represent values that are expected to be as likely to be accurate as not,

based on a random selection of watersheds. A comparable example is the statistic that the average American family has approximately 2 children; this may or may not be true for any individual family, but there is an equally good chance that it will be accurate for any randomly selected family, as that it will not be accurate. For the cumulative assessment, EPA is able accept this level of uncertainty in these estimates, precisely because it has confidence that aggregate exposures from the individual chemicals will be safe, based on the level of conservatism in the single chemical assessments. But given the statute's mandate to ensure a "reasonable certainty of no harm," EPA could not rely on the approach used under the cumulative assessment in the absence of the more conservative single-chemical assessment that evaluates the full range of exposures permitted by the registration.

Nevertheless, as discussed in the final rule, in response to FMC's concerns EPA performed a sensitivity analysis of an exposure assessment using a PCT in the watershed to determine the extent to which some consideration of this factor could meaningfully affect the outcome of the risk assessment. The results suggest that, even at levels below 10% CT, exposures from drinking water derived from surface waters can contribute significantly to the aggregate dietary risks, particularly for infants and children. Accordingly, these assessments suggest that use of a reasonably conservative PCT estimate, even if one could be developed, would not meaningfully affect the carbofuran risk assessment, as aggregate exposures would still exceed 100% of the aPAD.

*f. Objection/hearing request subissue: Natural surface water pH conditions.* The Petitioners contend that the low PCT levels guaranteed by the recent proposed use tracking system, along with natural surface water pH conditions in the areas where use is permitted under the revised label will ensure potential exposures are *de minimis*. In support they reference the analysis in Exhibit 16, which they claim demonstrates that the NAWQA USGS data show that average surface water pH is above 7.5 and that "in most regions, moving 2 standard deviations away from average (which would capture 95% of all observed values) results in pHs that are still greater than 7.5."

*i. Background.* In the proposed rule, EPA explained that the variation in pH across the landscape was a significant uncertainty in EPA's analysis. The proposal stated, that "while it is well established that carbofuran will degrade at higher rates when the pH is above 7, and lower rates when below pH 7, due to the high variation of pH across the country for many of the scenarios, a neutral pH (pH 7) default value was used to estimate water concentrations (73 FR 44883). Petitioners raised no issue regarding surface water pH in their comments.

*ii. Denial of hearing request.* EPA denies this hearing request because the objection, as well as the proffered evidence is untimely. EPA clearly described the potential impact that pH could have on its estimates, and noted that this was a significant uncertainty in its assessment. None of the analyses in Exhibit 16 were provided as comments on the proposed rule. Nor were any of the issues inherent in this objection raised as comments on the proposal. Since the proposed rule was clear that the issue was

relevant, and the NAWQA data were available, Petitioners could have conducted these analyses and raised the issue as part of their comments. Consequently EPA has determined that the evidence submitted in support of this objection is not appropriately considered as a basis for justifying a hearing on its final rule. And in the absence of this evidence, the objection consists of mere allegations and general denials, which do not warrant a hearing (40 CFR 178.32(b)(2)). Further, to the extent the objection and the evidence in Exhibit 16 rely on use tracking system and risk mitigation proposals submitted as part of their objections, this hearing request is denied as irrelevant, and therefore immaterial, as discussed in Unit VI.C. Petitioners are actually not objecting to the conclusions in EPA's final rule; rather, they are suggesting that EPA might reach a different result in a different factual scenario. Objections, however, must be directed "with particularity [at] the provisions of the regulation or order deemed objectionable" (21 U.S.C. 346a(g)(2)). In addition, for the reasons discussed in Unit VI.D, any hearing request premised on the new mitigation measures is considered untimely, and not appropriately considered at this stage of the administrative process as a basis for granting a hearing under the FFDCA.

EPA is also denying the requested hearing on the grounds that the evidence, even if established, is insufficient to justify the action urged (40 CFR 178.32(b)(3)). The analyses presented in Exhibit 16, as the Petitioners explicitly acknowledge, only capture 95% of the values; five percent of exposures are not, *per se, de minimis.* Second, just as with the groundwater pH analyses presented in Exhibit 14, no

information was provided to explain how the samples relate to the state or other geographic area in which carbofuran would be used. This is important because NAWQA samples were not evenly distributed across most states, but tended to be concentrated in particular regions; in statistical parlance, the samples were not collected randomly. In other words, no evidence was provided that would allow the Agency to determine the percentage of the carbofuran use area represented by the 95% of the samples the Petitioners' analysis addressed. Nor was any information provided to document the significance of the remaining 5% of the samples that were not captured by their analysis; for example, although this may have only represented 5% of the samples, it is not clear whether this 5% relates to only 5% of the areas where carbofuran may be used, or whether it actually represents a far greater percentage of the use area. Because this information, even if established, would provide an insufficient basis on which EPA could reasonably conclude that the drinking water exposures would be "safe," this issue is not determinative.

*iii. Denial of objection.* For the reasons presented above, the Petitioners' objection is denied. Further, there are several significant defects with the analysis in Exhibit 16. First, the analysis was based on statewide averages, which ignores the fact that pH is not evenly distributed, but randomly clustered. Second NAWQA contained no data for Kansas (KS), Oklahoma (OK), and South Dakota (SD); Petitioners simply assert that the "given the similarity between these states and the other High Plains states, it is reasonable to extend the observations from Colorado (CO), Nebraska (NE), and North Dakota (ND)" (Exhibit 16 at 4). Although

the 'High Plains' states all have extensive areas of grassland, they also have extensive geographic soil and climatic differences—*e.g.* the Black Hills and Badlands (SD), Sand Hills (NE), Flint Hills, Cheyenne Bottoms and Quivira wetlands (KS), Red Hills and Cross Timbers region (OK). These differences are not surprising since the distance from the Canadian border in ND to OK is over 1000 miles. Consequently it is not reasonable to extend observations from CO, NE, and ND to KS, OK, and SD.

*g. Objection/hearing request subissue: Effect of existing drinking water treatment systems.* The Petitioners contend that a review of drinking water treatment systems in areas under revised labels indicates that the majority of the "total population in affected states obtain their drinking water from surface water sources subject to lime softening or activated charcoal filters. They allege that "60% of the total population in affected states" will have their water treated by methods that will substantially reduce or entirely remove carbofuran concentrations. For the remaining 40%, they claim that a significant portion use ground water sources, which are already protected by the Petitioners' other mitigation measures, and the remainder are protected by the Petitioners' proposed use reporting scheme. In support of this objection, Petitioners rely on the analysis in Exhibit 17.

*i. Background.* In the proposed rule, EPA explained that one of the more significant uncertainties in EPA's analysis was that EPA failed to account for the potential effect of treatment in removing carbofuran from finished drinking water before it is delivered to the consumer supply system. EPA

explained that an evaluation of laboratory and field monitoring data indicate that carbofuran may be effectively removed (60-100%) from drinking water by lime softening and activated carbon; other treatment processes are less effective in removing carbofuran (Ref. 81). Although the Agency was aware of the mitigating effects of specific treatment processes, the processes employed at public water supply utilities across the country vary significantly both from location to location and throughout the year, and therefore EPA was unable to quantitatively incorporate this factor into its drinking water exposure estimates. For example, lime softening would likely reduce carbofuran concentrations. That process is used in 3 to 21% of drinking water treatment systems in the United States (Ref. 14). Activated carbon has been shown to also reduce carbofuran concentrations, but is used in 1 to 15% of drinking water treatment facilities (Id.). Petitioners noted this discussion in their comments, and relied on it to support their argument that their drinking water exposure assessments were conservative, because they did not account for the effect of treatment (Ref. 18 at 46-55). However they submitted no comments raising any of the issues or evidence presented in this objection.

*ii. Denial of hearing request.* EPA denies this hearing request on the grounds that both the objection and the proffered evidence are untimely. EPA clearly described the potential impact that treatment could have on its estimates. None of the analyses in Exhibit 17 were provided as comments on the proposed rule. Nor were any of the issues inherent in this objection raised as comments on the proposal. Since the proposed rule clearly identified the issue, and the

USGS data were available, the Petitioners could have conducted these analyses, or at least raised the issue, as part of their comments. Consequently, as discussed in Unit VI.D, EPA has determined that the evidence submitted in support of this objection is not appropriately considered as a basis for justifying a hearing on its final rule. In the absence of this evidence, the objection consists of mere allegations and general denials, which do not warrant a hearing (40 CFR 178.32(b)(2)). Further, to the extent the objection and the evidence in Exhibit 17 rely on the new registration proposals submitted in June 2009 as part of their objections, this evidence as well is deemed both immaterial and untimely. As discussed in Units VI.C and D, the new risk mitigation measures are not appropriately considered at this stage of the administrative process, and no hearing is warranted on this basis.

EPA is also denying this hearing request on the grounds the Petitioners' evidentiary proffer is insufficient to justify the factual issue urged (40 CFR 178.32(b)(2)). The analysis in Exhibit 17 is based on the percentage of the total population across all states combined, not the percentage of the local populations served by an individual surface water source—or even the percentage within each state. Even assuming that the 60% figure could legitimately be translated to a state-by-state basis, their own analysis shows that some percentage of the population in individual states will remain unprotected. In Colorado, only 24% of the population obtains their drinking water from groundwater, and in Illinois, only 33% of the population obtains their drinking water from groundwater. Sixteen percent of Colorado's population is not *de*

*minimis*. Consequently, even if the analysis were accurate, it would not provide a sufficient basis on which to conclude that exposures from drinking water would be "safe."

A further consideration in this regard is that drinking water exposures are driven by uniquely local factors; not only is the source of drinking water local (*i.e.*, a person drinks water from his or her local water system not from a combination of water systems from across the United States), but the likelihood and degree of contamination of any particular, local drinking water source, whether it is a reservoir or well, varies widely based on local conditions (*e.g.*, from local pest pressures, weather). Examining a population across an entire state-let alone across several states-is an entirely inappropriate basis on which to conclude that drinking water exposures will be safe.

The evidence submitted therefore does not support their contention that 60% of the population in "affected states" obtain their drinking water from public systems that use the treatment processes effective at mitigating carbofuran residues. For example, Exhibit 17 shows that a major Chicago surface water drinking water system, which serves a population of 9,000,000, has neither lime softening processes nor filters. Petitioners have submitted no evidence that this population is protected. The fact that a small population remains unprotected is not outweighed by the fact that a larger population in another community or state is protected. Their own evidence also shows that only 26 of 141 of community water systems use lime softening/filters (Exhibit 17 at 4-9), which supports the conclusion in the final rule that approximately 20% facilities have appropriate

treatment. See 57 FR 33244 (7/27/92) (Studies cited by NRDC do not provide a basis for the hearing because they "support the [FDA] conclusion in question."); 57 FR 6667 (2/27/1992) ("A hearing must be based on reliable evidence, not on mere allegations or on information that is inaccurate and contradicted by the record."); 49 FR 6672 (2/22/84) (no hearing if claim based on demonstrably false premise).

*iii. Denial of objection.* For the reasons discussed above, this objection is denied. A further consideration is that treatment does not necessarily remove all residues. As previously noted, in both the proposed and final rules EPA discussed the SDWA monitoring detections between 4 and 7 ppb, which represent concentrations in samples collected post-treatment. As such, these levels are of particular concern to the Agency. An infant who consumes a single 8-ounce serving of water with a concentration of 4 ppb, as detected in the monitoring, would receive approximately 130% of the aPAD from water consumption alone. An infant who consumes a single 8-ounce serving of water with the higher detected concentration of 7 ppb, as detected in the monitoring, would receive approximately 220% of the aPAD from water consumption alone.

*G. Objections to EPA's Dietary Risk Assessment*

Petitioners raise two related objections to the way in which EPA evaluated the aggregate dietary exposures to carbofuran residues. First they raise several technical challenges to the way in which EPA calculated the two recovery half-lives that were used in the risk assessment supporting the final rule to account for the potential for individuals to recover from the effect of ingesting carbofuran residues between

exposures. Second, they object to the fact that in the final rule EPA included both aggregate exposure estimates that did not account for the potential for individuals to recover from the effects between exposures as well as estimates that did account for such recovery. In support the Petitioners cite to Exhibits 9 and 10. Exhibit 9 is a memorandum prepared by Robert Sielken and Ciriaco Valdez-Flores. Exhibit 10 is a published literature study by Elsa Reiner that presents data on the rates of spontaneous reactivation of phosphorylated and carbamylated cholinesterases.

*1. Objection/hearing request subissue: Inclusion of exposure estimates that do not incorporate recovery in final rule.* The Petitioners object to the fact that the final rule presented aggregated exposure estimates that did not incorporate the anticipated recovery from carbofuran's effects between exposures, in addition to those that did account for recovery. They claim that recovery time should be included in EPA's "primary" risk assessment.

*i. Background.* As discussed in Unit V, EPA's standard acute dietary exposure assessment calculates total dietary exposure over a 24-hour period; that is consumption over 24 hours is summed and no account is taken of the fact that eating and drinking occasions may spread out exposures over a day. This total daily exposure generally provides reasonable estimates of the risks from acute dietary exposures, given the nature of most chemical endpoints. Due to the rapid recovery associated with some chemical toxicity (*e.g.*, AChE inhibition), 24-hour exposure periods may or may not be appropriate. To the extent that a day's eating or drinking occasions leading to high total daily

exposure might be found close together in time, or to occur from a single eating event, minimal AChE recovery would occur between eating occasions (*i.e.*, exposure events). In that case, the "24-hour sum" approach, which sums eating events over a 24-hour period, would provide reasonable estimates of risk from food and drinking water. Conversely, to the extent that eating occasions leading to high total daily exposures are widely separated in time (within 1 day) such that substantial AChE recovery occurs between eating occasions, then the estimated risks under any 24-hour sum approach may be overstated. In that case, a more sophisticated approach—one that accounts for intra-day eating and drinking patterns and the recovery of AChE between exposure events—may be more appropriate. This approach is referred to as the "Eating Occasions Analysis" and it takes into account the fact that the toxicological effect of a first dose may be reduced or tempered prior to a second (or subsequent) dose.

In the proposed rule, EPA conducted an Eating Occasion analysis based on two half-lives: 150 minutes and 300 minutes (73 FR 44887 (July 31, 2008)). These half-lives were not specific to carbofuran, but were calculations derived for the NMC Cumulative Risk Assessment. EPA concluded that incorporating these analyses into the risk assessment had little impact on the risk estimates from exposures from food alone, but that risk estimates from combined exposures from food and water were reduced by approximately 2-3X (Id). However, because many of EPA's risk concerns stemmed from a single exposure (e.g., one meal) and because, even when recovery was accounted for, aggregate exposures far exceeded safe levels, EPA

concluded that "risks to carbofuran is indeed not substantively overestimated using * * * the 24-hour approach" (Id).

In their comments, Petitioners complained that EPA had failed to incorporate recovery into their risk assessment. They further argued that EPA should calculate the per capita 99.9th percentile based on all person minutes rather than all person-days. In addition, they submitted an aggregate dietary risk assessment they had conducted using a 150-minute half-life input. They submitted no explanation for using only the 150-minute half-life rather than also including estimates based on the 300-minute half-life that EPA has used for the proposed rule.

In the final rule EPA explained that it had conducted a revised Eating Occasion analysis to evaluate the impact of carbofuran's rapid reversibility on its risk estimates (74 FR 23086 (May 15, 2009)). EPA concluded that incorporating Eating Occasion Analysis and the 186-minute or 426-minute recovery half-lives for carbofuran did not significantly change the risk estimates for food exposures alone (74 FR 23086 (May 15, 2009)). EPA concluded that risk estimates based on combined food and drinking water exposures are reduced considerably—by a factor of two or more in some cases, but nonetheless still substantially exceed EPA's level of concern for infants and children. EPA also explained that the Agency remains concerned about the risks from single eating or drinking events. Finally, EPA noted that the Eating Occasion Analyses underestimate exposures to the extent that they do not take into account carry-over effects from previous days, and because drinking

water concentrations are randomly picked from the entire 30-year distribution (Id at 23087).

*ii. Denial of hearing request.* EPA is denying this hearing request on two grounds. First, the objection fails to present a disputed issue of material fact. The record is clear that EPA did incorporate recovery into its analysis; indeed, one of Petitioners' objections relates to the manner in which EPA incorporated recovery into its risk assessment (Obj at 30-33). Rather, their only challenge is that the final rule should have only presented risk estimates that accounted for recovery. The sole issue is whether it was reasonable for EPA to have also communicated aggregate risks that did not account for recovery, when (1) EPA's estimates showed that accounting for recovery demonstrated that EPA's standard 24-hour estimates were not substantially overstated; (2) EPA's approach to accounting for recovery underestimates some risks; and (3) EPA's risk assessments concluded that infants received unsafe exposures from a single meal (eating occasion). This is a policy issue, and hearings are not appropriate on such (40 CFR 178.32(b)(1)).

Second, the fact that EPA relied on 24-hour aggregate exposures in addition to analyses that accounted for recovery is not material. As documented in the final rule, EPA would still have concluded that revocation of all tolerances were warranted on the grounds that, even accounting for recovery, aggregate exposures are not "safe." Even though accounting for recovery resulted in a 2-3X reduction in exposure estimates, many of EPA's estimates for aggregate exposures ranged between 2700% aPAD and 9400% aPAD for infants. Accounting for recovery does not, therefore, demonstrate that aggregate exposures will

be safe for infants. Of greater significance in this regard is EPA's finding that infants are at risk from a single exposure. Recovery is only relevant, by definition, where the risk is derived from multiple exposures over time.

*iii. Denial of objection.* The reason for not simply adopting the assessment incorporating recovery time was that the Agency has concerns that other aspects of its exposure model tends to understate exposure. If the assessment using recovery time had suggested that carbofuran risks may be acceptable, EPA would have had to further examine how exposure was assessed. However, because both the assessment based on 24-hour exposure and the one incorporating recovery time showed carbofuran exposures to be well over the safe level, EPA concluded that its exposure assessment was reasonable. As explained in the final rule, incorporating Eating Occasion Analysis and the 186-minute or 426-minute recovery half-lives for carbofuran resulted in a reduction in the risk estimates for which food and drinking water are jointly considered (*i.e.*, Food + Drinking Water) by a factor of two or more in some cases. But even though the risk estimates from aggregate exposure are reduced, they nonetheless still substantially exceed EPA's level of concern for infants and children. Using drinking water derived from the surface water from the Idaho potato surface water scenario, which estimated one of the lowest exposure distributions, aggregate exposures at the 99.9th percentile ranged from 328% of the aPAD under the scenario for which infants rapidly metabolize carbofuran (*e.g.*, 186-minute half-life), to a high of 473% of the aPAD under the scenario for which infants metabolize carbofuran more slowly (*e.g.*, scenarios in

which a 426-minute half life is assumed). Either way, the tolerances are unsafe.

Moreover, even accounting for the estimated decreased risk from accounting for carbofuran's rapid reversibility, for which recovery between exposures is irrelevant. The Agency remains concerned about the risks from single eating or drinking events, as illustrated in the following example, based on an actual food consumption diary from the CSFII survey. A 4-month old male non-nursing infant weighing 10 kg is reported to have consumed a total of 1,070 milliters (ml) of indirect water over eight different occasions during the day. The first eating occasion occurred at 6:30 a.m., when this 4 month old consumed 8 fluid ounces of formula prepared from powder. The FCID food recipes indicate that this particular food item consists of approximately 87.7% water, and therefore, 8 ounces of formula contains approximately 214 ml (or grams) of indirect water; with the powder (various nutrients, dairy, soy, oils, etc.) accounting for the remaining 12.3%. This infant also reportedly consumed a full 8-ounce bottle of formula at 12 p.m., 4 p.m., and 8 p.m. that day. The food diary also indicates that the infant consumed about 1 tablespoon of water (14.8 ml) added to prepare rice cereal at 10 a.m., about 2 ounces of water (59.3 ml) added to pear juice at 11 a.m., another 1/2 tsp of water (2.5 ml) to prepare more rice cereal at 8:30 p.m.; and finally, he consumed another 4 ounces of formula (107 ml) at 9:30 p.m.

The infant's total daily water intake (1,070 ml, or approximately 107 ml/kg/day) is not overly conservative, and represents substantially less than the 90th percentile value from CSFII on a ml water/kg bodyweight (ml/kg/bw) basis. As noted, carbofuran has

been detected in finished water at concentrations of 4 ppb. For this 10 kg body weight infant, an 8-ounce bottle of formula prepared from water containing carbofuran at 4 ppb leads to drinking water exposures of 0.0856 micrograms of active ingredient/kilogram of bodyweight (µg ai/kg bw), or 114% of the aPAD from that bottle alone. Based on the total daily water intake of 1,070 ml/day (no reversibility), total daily exposures from water at 4 ppb concentration would amount to 0.4158 µg ai/kg bw, or 555% of the aPAD; this is the amount that would be used for this person-day in the Total Daily Approach.

Peak inhibition occurs following each occasion on which the infant consumed 8 fluid ounces of formula (6 a.m., 12 p.m., 4 p.m. and 8 p.m.); however, the maximum persisting dose occurs following the 9:30 p.m. eating occasion, based on a 186-minute half-life parameter. This produces a maximum persisting dose of 0.1457 µg ai/kg bw, or about 30% of the total daily exposure of 0.4158 µg ai/kg bw derived above, or expressed as a fraction of the level of concern, the maximum persisting dose amounts to about 194% of the aPAD (or 30% of 554%). Note that with drinking water concentration at 4 ppb, an infant consuming one 8 oz bottle of formula—prepared from powder and tap water containing carbofuran at 4 ppb will obtain exposures of approximately 114% of aPAD. Since many infants consume the equivalent of this amount on a single eating occasion, accounting for reversibility over multiple occasions is not essential to ascertain that infants quite likely have obtained drinking water exposures to carbofuran exceeding the level of concern based on drinking water concentrations found in public drinking water supplies.

The approach discussed above is used to evaluate the extent to which the Agency's 24-hour approach to dietary risk assessment overestimates risk from carbofuran exposure. The results of both approaches indicate that the risk from carbofuran is indeed not substantively overestimated using the current exposure models and the 24-hour approach.

In this regard, it is important to note EPA's Eating Occasion Analyses underestimate exposures to the extent that they do not take into account carry-over effects from previous days, and because drinking water concentrations are randomly picked from the entire 30-year distribution. As discussed previously, DEEM-FCID is a single day dietary exposure model, and the DEEM-based Eating Occasion Analysis accounts for reversibility within each simulated person-day. All of the empirical data regarding time and amounts consumed (and corresponding exposures based on the corresponding residues) from the CSFII survey are used, along with the half-life to assess an equivalent persisting dose that produced the peak inhibition expected over the course of that day. This is a reasonable assumption for food alone; since the time between exposure events across 2 days is relatively high (compared to the half-life)—most children (>9 months) tend to sleep through the night—and the time between dinner and breakfast the following morning is long enough it is reasonable to "ignore" persisting effects from the previous day. A single day exposure model will underestimate the persisting effects from drinking water exposures (formula) among infants, and newborns in particular (<3 months), since newborns tend to wake up every 2 to 4 hours to feed. Any carry over effects may be important, especially if exposures

from the previous day are relatively high, since the time between the last feeding (formula) of the day and the first feeding of the subsequent day is short. A single day model also does not account for the effect of seasonal variations in drinking water concentrations, which will make this effect more pronounced during the high use season (*i.e.*, the time of year when drinking water concentrations are high). Based on these analyses, the Agency concludes that the current exposure assessment methods used in the carbofuran dietary assessment provide realistic and high confidence estimates of risk to carbofuran exposure through food and water.

In summary, there are several factors that may cause EPA's exposure/risk model to either understate or overstate exposure/risk. It is unreasonable to present risks only incorporating factors that tend to reduce exposure/risk estimates (*e.g.*, recovery time), as Petitioners suggest. EPA's approach of evaluating the impact that these factors may have on the risk assessment is an appropriate method of taking all relevant factors into account. Petitioners' objection to EPA's policy decision to present acute risks in terms of 24-hours of exposure is therefore denied because EPA's policy approach here is reasonable.

*2. Objection/hearing request subissue: Technical challenges to EPA's calculated half-lives.* Petitioners contend that EPA's calculation of carbofuran half-lives of 186 minutes and 426 minutes were flawed, and that the data instead support the use of a 150-minute half-life. Petitioners identify three specific challenges: (1) Because one of the time course studies showed that the time-to-peak effect was one hour, EPA's assumption that the time-to-peak effect in each study

was 15 minutes is incorrect; (2) EPA included the control rats in its modeling, which distorts the estimated recovery half-life because it incorporates AChE from animals that were not dosed and did not need to recover; (3) Biochemically, the recovery half-lives of all NMC chemicals should be the same, which supports the use of a 150-minute half-life. In support of these claims, Petitioners offered a summary of written testimony from Drs. Sielken and Valdez-Flores (Exhibit 9) and a published study (Exhibit 10).

*i. Background.* In the proposed rule, EPA relied on half-lives of 150 minutes and 300 minutes (73 FR 44887). These values were calculated for the NMC cumulative risk assessment and so were intended to encompass the half-lives for all of the NMC pesticides.

In the final rule, EPA calculated half-lives specific to carbofuran to ensure that its analyses accurately reflected carbofuran's risk. Using the two FMC time course studies in rat pups EPA calculated half-lives for recovery of 186 and 426 minutes (Id). The two values were derived from two different studies using rat pups of the same age (Refs. 24, 25); the two values provide an indication that half-lives to recovery can vary among juvenile rats. By extension, children are expected to vary in their ability to recover from AChE inhibition where longer recoveries would be associated with a potentially higher "persisting dose."

*ii. Denial of hearing request.* The issue of the appropriate half-lives for carbofuran is not material. Petitioners have proffered no evidence to show that reliance on a 150-minute half-life rather than a 186-minute half-life would make a significant difference to their estimates. By contrast, in the risk assessment supporting the final rule, EPA's estimates show that

the use of a 150-minute or 186-minute half-life makes little or no difference. For example, EPA's estimated exposures from food alone for children 1-2 were 43% of the aPAD, assuming a 186-minute half-life, and 41% of the aPAD, assuming a 150-minute half-life. Similarly, for infants, the estimates ranged from 31% aPAD, assuming a 186-minute half-life, and 30% of the aPAD, assuming a 150-minute half-life. For all other age groups, the estimated exposures were identical, whether one assumed a 150-minute or 186-minute half-life.

In any event, Petitioners' objection would have ultimately no effect on the Agency's conclusion that the carbofuran tolerances are not "safe." Given EPA's assessments showing that a single exposure can result in excessive risks to infants—a conclusion that Petitioners have not challenged—the extent of recovery between subsequent exposures is irrelevant. This conclusion alone provides an adequate basis to revoke the carbofuran tolerances. Accordingly, because the action would be the same even if the factual issue were resolved in the manner sought, this request does not meet the standard for granting a hearing (40 CFR 178.32(b)(3)).

There is yet a further consideration affecting the materiality of this objection. EPA's recalculation of half-lives in the final rule would ordinarily mean that Petitioners could appropriately challenge EPA's methodology for deriving the revised half-lives for the first time in their objections. This is because the Petitioners would have had no prior opportunity to challenge the manner in which these estimates were developed, as EPA had not previously relied on carbofuran-specific estimates. However in this case,

the Petitioners never commented on the 300-minute estimate EPA used in the proposal, nor raised any issue to challenge the reliance on a longer half-life to account for the variation in children's sensitivity. For the reasons discussed in Unit VI.D, they have therefore waived any objection to use of a 300-minute half-life. Accordingly, the question of whether the Petitioners' half-life of 150-minutes or EPA's estimated half-life of 186-minutes is immaterial, since the lower amount of recovery associated with the longer 300-minute half-life would be expected to have a far greater impact than the use of a 186-minute half-life.

EPA is also denying the hearing request because the evidentiary proffer in support of this objection is inadequate. Petitioners have not provided the underlying analyses conducted in support of their calculated half-lives. The remainder of Exhibit 9 consists of contentions that EPA's analyses were mistaken. In the absence of the analyses that support their claim that the data support a half-life of 150 minutes, Petitioners' evidentiary proffer consists of no more than mere allegations and denials. Hearings will not be granted on this basis (40 CFR 178.32(b)(2)) (See 73 FR 42706 (July 23, 2008) ("NRDC does no more than state '[w]e are aware of no statistical test' which would support EPA's use of the Gledhill data. As EPA's regulations make clear, a mere 'denial' of an EPA position is not sufficient to satisfy the standard for granting a hearing") (citations omitted); 53 FR 53176, 53199 (December 30, 1998) ("Rather than presenting evidence [the objector] asserts that FDA did not adequately justify its conclusions. Such an assertion will not justify a hearing.").

The published paper in Exhibit 10 does not cure this defect. The paper was submitted to support the claim that the Petitioners' 150-minute half-life is consistent with the "available literature on the AChE recovery" (Obj at 32). This evidence is immaterial. The Reiner paper relates to the reactivation of the AChE enzyme; however the relevant issue is not the reactivation of the cholinesterase enzyme, but the level of chemical in that target tissue, which this study does not address. Moreover, this study concludes that "[I]t follows from the data in Tables 1 and 2 that the rate of spontaneous reactivation cannot be predicted, but must be separately determined for each compound and each enzyme source (Exhibit 10 at 1). The paper did not include data specifically on carbofuran, and it is therefore difficult to see how this could be argued to support the Petitioners' half-life of 150-minutes.

*iii. Denial of objection subissue.* All of Petitioners' claims are incorrect.

*Appropriate time to peak effect.* The Petitioners claim that the time to peak effect in the study with MRID 47143704 (Ref. 2) should have been 1 hour instead of the 15 minutes EPA calculated. Petitioners chose this value simply by choosing the data point with the highest level of inhibition. But this approach is flawed in a number of regards: First as a practical matter, using the same criteria on which the Petitioners rely, the time to peak effect in MRID 46688913 (Ref. 3) is 15 minutes. Petitioners have presented no basis for excluding those results.

More significantly, the Petitioners' approach fails to account for the variability of the estimated AChE activity at each time point. As a point of background, the level of the highest inhibition is not something that

can be observed, in the way that motor activity is observed. To determine inhibition, samples are taken and measured-the samples may or may not capture the highest point of inhibition; the technician has not external indicia that will determine the moment of the "peak." Determining peak inhibition is estimated based on the available measurements. But because measurements are generally variable—the animals differ and the sampling itself is not identical, as people cannot perfectly replicate their actions time after time—in order to accurately capture the peak levels, the variability needs to be accounted for. When, as here, the individual values are quite variable, then for a half-life as long as carbofuran's, the sampling variability will make the study means bounce up and down around a trend line representing the true recovery rate. Figure 2 illustrates the sampling variability of the measured AChE activity and its relationship to EPA's modeling estimates for PND11 pups. In brief, this plots observed versus predicted for all the data. Each little point is an individual animal, while the time-group mean is the larger version of the same plotting symbol. The vertical lines are the 95 percent confidence intervals for each mean, the vertical lines. The diagonal line in each figure is the identity line-i.e., the line all the data would fall on if there were no variability and the model were perfect. Normally, one would expect some random scatter about the identity line. In such a case, simply visually picking the time with the lowest mean, which is what the Petitioners have done, will not be a very reliable way to estimate the time to peak effect.

[Figure 2 omitted]

*Inclusion of data from control animals.* It is standard scientific practice to include concurrent control animals (*i.e.*, animals that are not dosed with the test substance) as part of any experimental design. The purpose of controls is to determine the effects of the inevitable, unexpected, and uncontrolled variations in experimental practice, such as the biological variation between individual living animals. EPA's model simply used control levels to establish a baseline against which to evaluate the recovery of the treated animals. For example, as discussed above, measurements of AChE activities may change, and that concurrent controls are set up so that the same non-dose-related factors that affect treated animals will also affect control animals. Thus, EPA measured activity and computed inhibition based on measures of activity in treated animals and concurrent control animals. Thus, if the control animals showed that measured levels of AChE typically varied by 5 percent, if the dosed animal showed inhibition levels of 20 percent, EPA would consider that only 15 percent of the inhibition would be related to the chemical exposure. EPA did not estimate a half-life of recovery for the control animals and incorporate that into the estimated half-lives, which seems to be the Petitioners' allegation.

*Biochemically, the recovery half-lives of all NMC chemicals should be the same.* Although the Petitioners' claim that the recovery rate of AChE inhibited by carbamate compounds is dictated by the commonly-shared NMC carbamyl group is theoretically plausible, in reality, it is not supported by the data on the NMC compounds. EPA had originally hoped, based on the same mechanistic argument Petitioners

make, that half-lives would be the same across all NMCs, thus greatly simplifying the cumulative risk assessment. It turned out, though, in the NMC data sets analyzed for the NMC cumulative risk assessment, that estimated recovery half-lives changed (generally, they got longer) as dose increased, which is counter to the results that would be predicted from the Petitioners' simple mechanistic argument (Ref. 81). Ultimately, this is due to the fact that the relevant question is not the abstract reactivation of the cholinesterase enzyme, but the level of chemical in the living animal's target tissue, which is a function both of the pharmacokinetics of the NMC (*i.e.*, the rate at which the chemical is absorbed, distributed among tissues, and eliminated) in the animal and the rate of hydrolysis of the leaving group off the AChE molecule. These parameters vary at least somewhat for the different carbamates, accounting for the differences in half-lives between the NMC pesticides.

*H. Objection to EPA's Decision Not To Rely on Carbofuran Human Study*

Petitioners object to EPA's reliance on a default 10X interspecies factor, which accounts for the uncertainties inherent in extrapolating from animal data to the anticipated effects in humans. They argue, for several reasons, that EPA should have instead used a 3X interspecies factor. All of their arguments, however, depend on EPA consideration of an oral carbofuran dosing study conducted in humans. EPA did not rely on the cited human study because it found, taking into account the advice of the HSRB, that the study was scientifically invalid. EPA's Human Research rule prohibits EPA from considering scientifically invalid human studies (40 CFR 26.1701).

In their objections, Petitioners argue that the HSRB's, and presumably EPA's, evaluation of the scientific validity of the human study was flawed because (1) the human study was not considered in light of the animal data on carbofuran; (2) insufficient weight was given prior independent reports on the value of the Arnold study which reached the opposite conclusion from the HSRB; (3) the "technical" concerns raised by the HSRB are addressed by "the data within the study" and that these "technical" deficiencies do not render the Arnold study unreliable.

*1. Background.* There are three intentional dosing human studies conducted with carbofuran that were conducted by J.D. Arnold in 1976, 1977, and 1978. One study was an oral ingestion toxicity study and two studies were intended to evaluate toxicity from dermal exposure (Refs. 7, 8, 9). The oral study conducted with carbofuran was carried out in nine healthy male volunteers using an ascending dose schedule and single doses of 0.05, 0.1 and 0.25 mg/kg (Ref. 7). The two dermal toxicity studies were found to have significant ethical deficiencies and the EPA's Human Studies Review Board recommended against their use. The Petitioners do not challenge the decision to disregard these studies.

As previously noted, EPA did not rely upon any of the existing intentional dosing human toxicity study deriving an acceptable level of exposure for carbofuran. Instead, EPA relied on data conducted with rats, and applied the default 10 x interspecies factor to account for the potential uncertainty in extrapolating from animal data. EPA's decision not to rely on the Arnold studies was made pursuant to its Human Research rule. As explained in Unit III.B, that rule establishes

different ethical standards for the review of completed human studies depending on whether they were initiated before or after the effective date of the rule on April 7, 2006. For an intentional human exposure study such as the Arnold studies, that was initiated prior to April 7, 2006, EPA is barred, subject to a very limited exception, from relying on it if there is clear and convincing evidence that the conduct of the research was fundamentally unethical or significantly deficient with respect to the ethical standards prevailing at the time the research was conducted (40 CFR 26.1704, 26.1706). Further, the rule limits the human research that can be relied upon by EPA to "scientifically valid and relevant data" (40 CFR 26.1701). Finally, because the Arnold study was conducted with the purpose of identifying or measuring a toxic effect, EPA is required by the rule to submit its determination regarding these issues to an independent expert advisory body known as the Human Studies Review Board ("HSRB") for review. These procedures were followed with regard to the Arnold study.

The HSRB reviewed the Arnold oral and dermal carbofuran human studies at its May, 2006 meeting (Refs. 7, 8, 9). The Board found numerous technical deficiencies regarding the conduct of the oral study and that overall, the weaknesses of the studies far outweigh the strengths. These deficiencies included: (1) There was no justification or rationale for the selection of doses used in any of the three studies. (2) The sample size was very small (typically two subjects per dose or condition) with few or no controls (no more than two control subjects in any study). Such a design prevented evaluation of statistical significance

for any parameter measured in the studies. (3) The values obtained for RBC and plasma cholinesterase levels were highly variable. Factors that contributed to this variability included the small sample size, the inclusion of only a single baseline sample collected immediately prior to dosing used to compare all post-dosing samples, the small number of control subjects, and an uncommon method for analytical determination of cholinesterase activities. The contribution of potential laboratory error cannot be ruled out. (4) Plasma cholinesterase levels were highly variable in all studies so as to preclude any useful interpretation. In general, plasma cholinesterase levels were not consistent with changes in RBC cholinesterase activities. (5) One subject who presented with abnormal vestibular mechanisms in the pre-dose evaluation was used in the oral study and showed serious symptoms after treatment. (6) Subjects were allowed to smoke during the study period.

In response to a specific request from the Agency, the Board provided additional analysis concerning the potential for the data in human subjects for carbofuran to be applied to: (1) The calculation of a benchmark dose ($BMD_{10}$) and identification of the $BMD_{10}$ L (lower confidence limit); (2) the identification of a NOAEL or LOAEL for effects or (3) the comparison to other species for possible adjustments to uncertainty factor for the cumulative assessment. The HSRB provided the following additional perspective relative to the Agency's question:

> The utility of the human studies with carbofuran was limited by the very small sample size used in all of the studies. The Agency proposed to use the RBC cholinesterase data for

determination of the $BMDL_{10}$. However, under conditions where the group size was only two, it would be imperative to have highly accurate, valid, reliable and consistent measures of RBC cholinesterase activity in both control and carbofuran-treated subjects. This rigor was simply not achieved in the human studies. Rather, RBC cholinesterase activities were compared to a single baseline value, were highly variable across subjects, including controls, and did not show any consistency with plasma cholinesterase levels. As such, although EPA scientists calculated a $BMDL_{10}$ from the time course of changes in RBC cholinesterase values in the nine subjects evaluated in the oral study, the HSRB concluded that the accuracy and reliability of this calculation was limited by the technical shortcomings noted for the study. Therefore, the HSRB reiterated its recommendation that the $BMDL_{10}$ calculated by the Agency from the human data should not be used.

In a similar manner, the small sample size, compounded by the lack of consistent changes in cholinesterase activities in all studies, the inappropriate methods used for dermal application of the compound in the dermal studies and the inclusion of at least one subject who presented with abnormal vestibular function in a pre-dose assessment limited the general utility of the data. Collectively, the weaknesses in the conduct and outcomes of the carbofuran human studies cast doubt on the utility of the data for identifying a NOAEL or LOAEL or for

> comparing across species in consideration of the interspecies uncertainty factor for the cumulative risk assessment. Thus the majority of HSRB members agreed the human oral data should not be used to identify a NOAEL or LOAEL, and there was unanimous agreement that the human dermal data should also not be used for these evaluations.

The HSRB concluded that while these studies were informative, due to the numerous technical issues regarding the conduct of the oral study, overall, the weaknesses of the studies far outweigh the strengths. Describing the studies as "poor science," the HSRB recommended against the use of the oral study conducted with carbofuran in human subjects for the single chemical assessment or in informing the interspecies uncertainty factor for the cumulative assessment.

In their comments opposing EPA's proposal to revoke carbofuran tolerances, Petitioners essentially raised the same arguments they present in their objections.

In responding to Petitioners' comments, EPA explained that it agreed with the HSRB's conclusions that the studies were scientifically flawed, and that, therefore, under the Human Research rule, EPA was barred from considering them (Ref. 85 at 9).

*2. Denial of hearing request.* The critical issue here is EPA's determination under the Human Research rule that the Arnold study was scientifically invalid. All of Petitioners' arguments concerning the choice of the interspecies safety factor rely on EPA's consideration of the Arnold study. As noted above, Petitioners make three arguments as to why EPA

erred in its determination. For the reasons discussed below, none of those arguments satisfy the regulatory standard for granting a hearing. Further, as explained in Unit VI.H.3., Petitioners' objections to EPA's determination have no merit. Thus, there is no need to consider Petitioners' more general arguments about EPA's decision to use a 10X interspecies factor in assessing carbofuran's risk.

Petitioners' first argument as to why EPA erred in its determination that the Arnold study was scientifically invalid is that EPA failed to consider the animal data on carbofuran in assessing the scientific quality of the Arnold study. This claim is not material and thus not appropriate for a hearing (40 CFR 178.32(b)(3)). Under the Human Research Rule, the relevant question is whether the Arnold study is scientifically valid, not whether consideration of the Arnold study in conjunction with the animal data could justify a lower interspecies factor. EPA, and the HSRB, found the Arnold study to be flawed at its core—due primarily to its small sample size and the high variability in measurement of AChE inhibition—and no amount of data from other studies in animals can cure these defects in the Arnold study. Thus, Petitioners' claim here is irrelevant and immaterial to EPA's decision. Ultimately, Petitioners' objection is a challenge to the policy established in the Human Research rule that EPA will not routinely consider all human data. They contend that "[s]ince [human] data exist for carbofuran, they should have been used to select the interspecies uncertainty factor." However, this policy question is not open for debate under the terms of the Human Research rule. And more

importantly, such a question does not provide a basis for a hearing (40 CFR 178.32(b)(1)).

Second, Petitioners argue that insufficient weight was given the prior independent reports on the Arnold study. However, the weight EPA should give under the Human Research rule to pre-rule independent reviews as opposed to the conclusions of the HSRB—the body established by the rule for the purpose of aiding EPA's implementation of it—is a legal/policy question and not a factual one. Hearings will not be granted on legal/policy issues (40 CFR 178.32(b)(1)).

Finally, Petitioners' claims that EPA and the HSRB identified merely "technical" deficiencies in the Arnold study and that these deficiencies are "address[ed]" by "data within the study itself" and, therefore, do not render the study "unreliable" are no more than mere allegations and thus provide an insufficient basis for the granting of a hearing (40 CFR 178.32(b)(2)). Petitioners have proffered no evidence regarding the "technical" nature of the deficiencies in the Arnold study or how the deficiencies in sample size or variability are addressed within the study. Moreover, the record is clear that the deficiencies in the study are fundamental in nature and a hearing will not be granted on bald objections that are contradicted by the record (73 FR 42696 (July 23, 2008) (hearing denied when objection was contradicted by record and no evidence proffered in support)).

*3. Denial of objection.* Petitioners have offered no response to EPA's explanation for accepting the HSRB's reasoning as to the weaknesses of the studies that rendered them scientifically invalid. Specifically, Petitioners do not address the HSRB's conclusion, adopted by EPA, that "the weaknesses in the conduct

and outcomes of the carbofuran human studies cast doubt on the utility of the data for * * * comparing across species in consideration of the interspecies uncertainty factor." Nor do Petitioners offer any reason as to why the HSRB's conclusion is not "justifiable" in light of the individual peer review reports from Drs. Brimijoin, Chambers, and Pope. Actually, there are several very good reasons for EPA to place primary weight on the HSRB's report compared to the three individual reports from Drs. Brimijoin, Chambers, and Pope prepared in 1997. First, the prior reports were not produced under the rubric of the Human Research rule, which has a different scope of inquiry than a traditional peer review. Second, Drs. Brimijoin, Chambers, and Pope made their recommendation regarding use of the Arnold study for a RfD in the context of a very different overall database for carbofuran. A significant number of new toxicity studies have been submitted since 1997. Third, Drs. Brimijoin, Chambers, and Pope all noted the severe deficiencies in the Arnold study but proposed that they be dealt with through the use of additional safety factors. Given these considerations it was reasonable for EPA to place primary reliance on the HSRB's report.

The bulk of Petitioners' argument concerning EPA's determination on the scientific validity of the Arnold study is devoted to suggesting that the HSRB's review of the Arnold study was somehow "inadequate" because two members of the HSRB (Drs. Brimijoin and Chambers) were recused from the review due to their prior participation in a prior independent peer review. Petitioners also assert that the HSRB was hampered because EPA "never informed the HSRB that it could

call upon these experts for questioning or information regarding their prior peer review of the human studies, nor was it informed of—or provided with—those prior reviews."

These claims are wholly without merit. As laid out in a letter responding to FMC's complaint regarding the recusal of Drs. Brimijoin and Chambers from the HSRB review of the carbofuran human studies, the recusal was entirely appropriate, and consistent with EPA's policies and regulations. The facts outlined in that letter also demonstrate that the HSRB's review was in no way restricted or hampered by the limited recusal of the two Board members.

First, the HSRB was fully apprised of the earlier peer review reports. EPA relied on the reports because EPA's position before the HSRB was that the Arnold study should be found to meet the standard of the Human Research rule and would be useful in establishing points of departure for the carbofuran's single chemical assessment and in informing the interspecies uncertainty factor for the NMC CRA. It was clearly in EPA's interest that the HSRB be made aware of the earlier reports. In fact, the background materials provided to the Board included the peer review reports by Drs. Brimijoin, Chambers, and Pope, and the Agency's Weight-of-the-Evidence presentation to the HSRB which noted the contributions of these reviewers. Further, both the peer review reports and EPA's Weight-of-Evidence presentations were included in the public docket for the HSRB review. To the extent that the HSRB was still somehow unaware of the prior reports, FMC clearly referenced them in both its written and oral comments to the Board.

Second, EPA's determination on the recusal of Drs. Brimijoin and Chambers was clearly consistent with Agency policy and well with EPA's discretion. The EPA's Peer Review Handbook (3rd Edition) (Ref. 80) provides guidance about peer review processes of the Agency. Of particular relevance is the Handbook's guidance regarding independent peer reviewers. While the Handbook notes that there is no prohibition against using the same peer reviewer more than once on the same product, it nevertheless advises that "it is preferable to use different people each time to provide a broader perspective (Ref. 80 at 13). Further the Handbook advises that the review of experts who "have participated substantially in the development of a product * * * may not qualify as unbiased, independent peer review * * *" (Id.). Therefore, EPA concluded that, under the circumstances, a question could be raised regarding the impartiality of Drs. Brimijoin and Chambers from the particular matter under review by the HSRB. Further support on this point can be found in the regulations at 5 CFR 2635.502(a)(2), and in the preamble to the original regulation (56 FR 33778 (July 23, 1991)).

In light of these considerations, EPA addressed the appearance issue regarding Drs. Brimijoin and Chambers by determining whether authorization by the Agency designee should be invoked (see, 5 CFR 2635.502(d)). Three factors were particularly relevant to the determination of Drs. Brimijoin and Chambers (see, 5 CFR 2635.502(d)(4), (5), and (6)): the sensitivity of the matter, the difficulty of reassigning the matter to another employee, and adjustments that may be made in the employee's duties that would reduce or eliminate the likelihood that a reasonable person would

question the employee's impartiality. After considering these factors, the Agency decided the prudent course was be to recuse Drs. Brimijoin and Chambers from the HSRB carbofuran discussion but to authorize limited, as needed, participation.

As documented in Dr. William Farland's May 1, 2006 memorandum entitled, "Ethics Determination for Participation at the May 2-3, 2006 EPA Human Studies Review Board Meeting" (Ref. 39), EPA authorized the HSRB to ask Drs. Brimijoin and Chambers clarifying questions regarding their 1997 review, in the event that the HSRB deemed it necessary as part of their deliberations. At no point during the meeting did any of the HSRB's members indicate in any way that they wanted to consult with their recused colleagues. Nor did any of the members state that they wanted clarification on any point associated with the study.

For all of the above reasons, Petitioners' objection on this point is denied.

*I. Objections to Revocation of Import Tolerances*

Petitioners object to EPA's revocation of the tolerances for imported foods along with the tolerances associated with domestic uses. Petitioners allege that the revocation of the import tolerances is not supported by the available data because EPA's own risk assessments conclude that, when considered separately from the domestic uses, the residues from imported foods covered by these tolerances are "safe." Petitioners further argue that EPA "has not asserted any claim or rationale in the Final Order justifying its conclusions that the import tolerances are unsafe" and therefore the revocation is unjustified.

*1. Background.* In the proposed rule, EPA explained that its finding that aggregate exposure from

all of the existing uses of carbofuran is not safe does not necessarily mean that no individual tolerance or group of tolerances could meet the FFDCA 408(b)(2) safety standard and be maintained (73 FR 44865 (July 31, 2008)). Rather, to the extent parties wanted to retain a particular subset of existing tolerances, the onus was on commenters to identify those uses and to submit information to demonstrate that the tolerance(s) meet the statutory standard. Indeed, EPA specifically identified the import tolerances as a subset that might meet the safety standard (Id.).

No one submitted any comments alleging the need to retain individual tolerances for purposes of imports, or indicated an intention to seek to maintain those tolerances. The only subset of tolerances that commenters suggested was safe was the subset identified by the Petitioners, which included the import tolerances along with four domestic food uses.

In the final rule, EPA analyzed the aggregate exposures from the subset of tolerances the Petitioners sought to retain, and concluded that the aggregate residues from food covered by those tolerances and from residues in drinking water are unsafe (74 FR 23084-23088).

*2. Denial of hearing request.* A hearing is denied on this subissue because there is no disputed factual matter for resolution at a hearing. As the objection notes, EPA and Petitioners' risk assessment both concluded that the residues from imported food alone fell within the risk cup (Obj. at 52-54). The only issue this objection raises is whether EPA should have independently determined to retain a subset of the tolerances that Petitioners sought to maintain. This is a legal issue, and hearings are not appropriate on such

issues (40 CFR 178.32(b)(1)). (See 73 FR 42696-42697 (July 23, 2008) (denying NRDC's request for a hearing on objection that children's safety factor could not be reduced in absence of endocrine screening data). FDA also has repeatedly confirmed that the application of a legal standard to undisputed facts is a question of law for which a hearing is not required. (*See, e.g.*, 68 FR 46403, 46406 n.18, 46408, 46409 (August 5, 2003) (whether facts in the record show there is a reasonable certainty of no harm is a question of law; whether a particular effect is a "harm" is a question of law)).

In addition, Petitioners failed to raise this issue as part of their comments on the proposed rule, and never requested retention of only the import tolerances. Accordingly, as discussed in Unit VI.D, EPA considers this issue to have been untimely raised, and therefore waived. (See, 73 FR 42,696 (July 23, 2008) (denying NRDC's hearing request on claims not presented in their original petition); 72 FR 39318, 39324 (July 18, 2007) (ruling that parties may not raise new issues in filing objections to EPA's denial of original petition)).

*3. Denial of Objection.* Petitioners incorrectly allege that EPA provided no rationale for the revocations of the import tolerances. In the final rule, EPA clearly found that the aggregate exposures to carbofuran residues from all remaining uses, when combined with residues found in drinking water, were unsafe (74 FR 23084-23088 (May 15, 2009).

EPA can only maintain tolerances that it can determine will be "safe" within the meaning of section 408(b)(2)(A)(ii). In making this determination, EPA must consider aggregate exposures from "dietary exposure under the tolerance and all other tolerances in effect for the pesticide chemical residue, and

exposure from other non-occupational sources" (21 U.S.C. 346a(b)(2)(D)(vi)). At the time of the final rule, EPA evaluated the safety to the public from all dietary exposures to residues of carbofuran, which included not only the import tolerances, but also from residues on foods associated with domestic registrations and from residues in drinking water contaminated by the domestic uses. Indeed, until domestic use ceases—or at least until EPA has a reasonable basis to believe that it will cease—the Agency has no discretion to ignore the exposures from those uses. And revocation of the tolerances themselves does not necessarily resolve the issue, given the circumstances here. Until the registrations are cancelled, residues from contaminated drinking water, which is the primary contributor to the risks, must be included in EPA's risk assessment (Id).

The consequence of this requirement is that, when one tolerance is unsafe, all tolerances are equally unsafe until aggregate exposures have been reduced to acceptable levels. Accordingly, in circumstances where aggregate exposures exceed the risk cup, there are potentially multiple variations of the potential subset of tolerances that might meet the safety standard. FFDCA section 408 does not compel EPA to determine the appropriate subset that would meet the safety standard. EPA is compelled "to revoke or modify a tolerance if [EPA] determines it is not safe," but the statute grants EPA the discretion to determine how to proceed where more than one tolerance is unsafe. EPA's general policy in such situations is not to independently select the subset that meets the standard, but to rely on the pesticide registrant and the public to determine which of the various subsets of

tolerances are of sufficient importance to warrant retention. There are a number of reasons EPA adopted this policy; it would be an unreasonable burden for the Agency to evaluate every possible combination of tolerances that might fit within the risk cup. In addition, if there were multiple different combinations that might within the risk cup, it is not clear that any party would agree that EPA had selected the appropriate combination of tolerances. This is particularly relevant, since EPA relies on individual entities to maintain the tolerance, by continuing to submit necessary data to demonstrate the continuing safety of the covered residues.

*J. Summary of Reasons for Denial of Petitioners' Objections and Hearing Requests*

*1. General Denial.* All of Petitioners' objections and hearing requests are denied because they are irrelevant, and thus immaterial, to EPA's final regulation revoking carbofuran tolerances. The lack of relevance stems from Petitioners' decision to object not to the safety decision EPA made in its final revocation regulation but to instead argue that EPA should reach a different decision based on FMC's proposed changes to the carbofuran registration that were submitted to EPA 44 days after the regulation published in the **Federal Register**. These proposed registration changes are central to and inextricably intertwined with the contention that underlies all of Petitioners' objections-that the carbofuran tolerances are safe, because in order to retain the contested tolerances, Petitioners must succeed on all of their objections. There exist statutory and regulatory procedures under FIFRA for FMC to pursue an amended carbofuran registration. As part of seeking an amended

registration, FMC may petition to reestablish the revoked carbofuran tolerances. However, it is not proper to object to a final FFDCA tolerance revocation regulation based on the assertion that subsequently-filed, and as of yet unapproved FIFRA registration amendments, may change the risk picture under the FFDCA.

FMC has had ample opportunity prior to issuance of the final tolerance revocation regulation to amend its FIFRA registration, whether during the comment period on the proposed rule, the extended reregistration process, or the public process initiated as part of the NOIC for carbofuran. And FMC has requested a number of modifications to its registrations during that time period. Yet, FMC has waited until EPA issued a final revocation regulation finding that carbofuran tolerances are unsafe, particularly as to infants and children, before filing its latest series of proposed FIFRA registration amendments. For this FFDCA proceeding, that is too late. The FFDCA commands that EPA "shall modify or revoke a tolerance if the Administrator determines it is not safe" (21 U.S.C. 346a(b)(2)(A)(i)). The statute also places EPA under a special injunction to protect infants and children from the risks of pesticides (21 U.S.C. 346a(b)(2)(C)). EPA has made a final determination that carbofuran tolerances are unsafe and further determined that that lack of safety falls hardest on infants and children. Petitioners had the statutory right under FFDCA to challenge the accuracy of EPA's safety finding on carbofuran tolerances. FMC also has the statutory right under FIFRA to request amendment of its registration. What Petitioners may not do is prolong the FFDCA

tolerance revocation process by challenging EPA's safety determination based on proposed FIFRA registration changes that were not before EPA at the time of its final revocation decision.

*2. Alternate Grounds for Denial.* Despite the fact that Petitioners' objections and hearing requests are facially defective for reliance on newly-proposed FIFRA registration amendments, EPA has carefully examined each of Petitioners' objections and hearing requests and found that, in every instance, there are alternate grounds for denial. Those grounds are summarized below.

There are multiple problems with Petitioners' hearing requests. Many of these problems stem from the Petitioners' decision to withhold analyses and information from the notice-and-comment rulemaking portion of this proceeding. Thus, despite EPA's clear warning that issues not raised in comments on the proposed rule, and information not submitted in that same timeframe, would be considered waived, Petitioners included several new issues, and numerous documents and analyses for the first time with their objections although they were clearly available earlier. Petitioners also have, for the most part, ignored how EPA responded to the comments they did submit in the notice-and-comment rulemaking, and instead have often merely recycled their earlier comments as objections without addressing the reasons why EPA found them lacking in the first instance. This strategy, unfortunately for Petitioners, is fatal to many of their hearing requests and objections. EPA will not grant hearings on issues that have been waived, on issues where supporting documents were untimely submitted, or on claims that have become stale in that EPA

addressed them in the final rule and Petitioners have not responded by clarifying where disputed issues still remain.

It is not as if Petitioners lacked warning that EPA would take such an approach. Not only did EPA clearly state in the proposed rule that comments and information must be submitted in the comment period to be preserved but in 2007 EPA denied a hearing to a party who treated the notice-and-comment rulemaking process in a similarly cavalier fashion. In that instance, the party in question, like Petitioners, filed objections that largely mirrored its earlier submissions to the Agency without taking into account how EPA's final action had altered the nature of issues in dispute (See, *e.g.*, 73 FR 42693 ("NRDC's objections largely restate the claims in its petition. Significantly, NRDC does not acknowledge or respond to the DDVP dietary and residential risk assessments made in response to the NRDC petition.")). Such objections and hearing requests were denied for a lack of materiality (73 FR 42698-42699 ("When an objector does not challenge EPA conclusions in the section 408(d)(4)(iii) order but rather challenges some prior conclusion that was superseded by the section 408(d)(4)(iii) order, the objector has not raised a live controversy as to an issue material to the section 408(d)(4)(iii) order.").

*a. Children's Safety Factor Objection.* In support of their objection on the children's safety factor, Petitioners put forward several arguments; EPA summarizes below the various reasons for rejecting Petitioners' hearing requests and objections on each argument. Given the voluminous number of arguments asserted by petitioners in support of this objection, it is easy to lose track of the fact that all of the arguments

relate to a single decision by EPA—the decision to reduce the presumptive 10X children's safety factor to 4X, rather than to 1X or 2X as the Petitioners desire.

*(i) Subissue: Are brain AChE measures in juveniles adequately protective of CNS effects in juveniles?* EPA based its determination to reduce the children's safety factor to 4X on the ratio of sensitivity shown between carbofuran's effects on RBC AChE and brain AChE in juvenile rats. It is EPA's general policy to rely on RBC AChE as a surrogate for effects on the PNS but Petitioners failed to provide adequate RBC AChE data in juveniles to fully characterize the dose level of concern for PNS effects in infants and children. Petitioners claim EPA was wrong from the start. They claim that once EPA determined it had adequate data on brain AChE, the RBC data was irrelevant because brain AChE is an adequately-protective surrogate for PNS effects.

Petitioners' hearing requests and objections on this issue are denied for identical reasons: the available evidence identified by petitioners is "insufficient to justify the factual determination urged" (40 CFR 178.32(b)(2)). The critical issue with regard to EPA's children's safety factor decision is whether EPA has reliable data to ensure that residues of carbofuran in food will not cause adverse effects on infants and children's PNS. Petitioners claim that carbofuran data on brain AChE in juveniles is such reliable data. However, the evidence they proffer to support such an assertion is facially insufficient. Primarily, Petitioners cite data involving comparisons of brain AChE and PNS effects in adult animals. But evidence from adult animals is beside the point; the question is whether brain AChE in juveniles is protective of the PNS in

juveniles. For at least 25 years, EPA has required toxicity tests be performed with pre- and post-natal animals as well as adult animals because young animals can be more sensitive and affected in a different manner than adults. Further, the only studies Petitioners cite that compared brain AChE in juveniles with PNS effects in juveniles, were conducted using other pesticides. For good reason, EPA requires that pesticides be individually tested in toxicity studies. Moreover, the majority of the data cited by Petitioners in other chemicals actually fails to demonstrate that the brain is more sensitive than the PNS, and the remainder of the evidence is, at best, merely equivocal on this point.

To reiterate, if EPA chooses to select a children's safety factor different than 10X, it bears the statutory burden of showing that reliable data support its determination that the selected factor is safe for infants and children. Thus, Petitioners, in seeking to establish that EPA erred by not selecting an even lower children's safety factor for carbofuran (in fact, no such factor at all), similarly bear the burden of showing that there are reliable data for the proposition that juvenile brain AChE data for carbofuran are protective of PNS effects in children. Petitioners' equivocal and largely irrelevant proffer cannot meet that standard, particularly where EPA is lacking data it has traditionally-required on cholinesterase-inhibiting pesticides to protect against PNS effects, and the data EPA does have on measures of PNS effects indicate that effects on the juvenile PNS occur at lower doses than effects on brain AChE.

*(ii) Subissue: Are RBC AChE measures adequately reliable evidence of CNS effects?* As a

corollary to their claim that brain AChE measures are adequately protective of PNS effects, Petitioners also argue that RBC is not an appropriate surrogate for CNS effects in most circumstances. A hearing is not warranted on this subissue because Petitioners' evidentiary proffers either concern matters of undisputed fact (*e.g.*, RBC AChE inhibition is not an adverse effect, RBC AChE can be variable at low doses) or inadequate and irrelevant data on other pesticides. Further, Petitioners' claim basically reduces to an argument over which is the "preferred" surrogate for PNS effects in the absence of data directly measuring such effects. Thus, this subissue is an argument about science policy and EPA's regulations are clear that hearings will not be held on policy matters. Even more problematic to Petitioners' hearing request on this subissue is its lack of materiality. Having failed in the previous subissue to proffer sufficient evidence to show carbofuran brain AChE data in juveniles is protective of carbofuran's effect on the PNS in juveniles, Petitioners' attempt to attack EPA's basis for addressing carbofuran's effects on the PNS in juveniles can only undercut Petitioners' ability to demonstrate the safety of the carbofuran tolerances. With the demise of Petitioners' brain AChE argument, EPA's analysis of the RBC AChE data is the only remaining basis for reducing the children's safety factor. If Petitioners are successful in showing that RBC AChE data are not a reliable measure of PNS effects in juveniles, EPA would have no reliable data on such impacts and would be required to retain the full children's safety factor. As such, Petitioners' claim is immaterial; even if the claim were upheld, it would not justify the ultimate relief sought by Petitioners.

As to Petitioners' objection to EPA's science policy decision to use RBC cholinesterase as a surrogate for PNS effects, EPA explains in detail in Unit VI.E, the biological basis for its policy decision, the multitude of data supporting its approach, and the frequent consultations with the SAP concerning the wisdom of using such an approach. The equivocal data submitted by Petitioners does not raise a serious question regarding EPA's policy. In any event, as noted with regard to the hearing request, this subissue lacks materiality in that success on this subissue by Petitioners would retard rather than advance their challenge to EPA's action.

*(iii) Subissue: Is "lip-smacking" a CNS or PNS effect?* Petitioners object that EPA's evidence of "lip smacking" in a carbofuran adult developmental rat study does not support concern for potential PNS effects because lip smacking is more properly correlated to CNS, rather than PNS inhibition. A hearing is denied on this issue because Petitioners did not raise this issue in its comments on the proposed tolerance revocation. A hearing on this issue is also inappropriate because the issue is immaterial. EPA's decision that a 4X children's safety factor is appropriate did not rest exclusively—or even significantly—on the effects observed in this developmental study. Rather, EPA retained the children's safety factor based on the lack of data in the PNS and/or a surrogate at the low end of the response curve, and the fact that the available pup RBC data at higher doses affirmatively indicate that the PNS appears to be significantly more sensitive than the CNS.

Petitioners' objection on this subissue is denied because both parties agree that muscle fasiculations, which are the movements EPA described at the SAP meeting and in the proposed and final rules, are PNS-mediated effects. Further, it is unclear that the effects described in the studies Petitioners submitted are actually the same effects seen in the carbofuran study; other factors in the studies suggest that the movements being studied are not purely cholinergic, which calls into question whether the effects are the same. For the same reason, this calls into question the contention that the effects are exclusively CNS-related. Finally, the cited studies fail to support Petitioners' remaining contentions. Since it is unclear that the studies actually describe the same effects, and Petitioners have failed to demonstrate that the effects are exclusively CNS-related, the evidence does not, therefore, rebut EPA's conclusions regarding the movements described in the carbofuran study.

*iv. Subissue: Did EPA err by relying on studies not conducted pursuant to EPA's GLP regulations?* Petitioners claim that EPA's reliance on the ORD data is problematic because the data were not conducted in accordance with EPA's GLP regulations at 40 CFR part 160. Petitioners have not cited any evidence suggesting there is a substantive problem with the ORD data or made any arguments to such effect. Thus, this subissue presents only a legal question and legal questions are not appropriate grounds for a hearing. EPA denies Petitioners' objection on this point because EPA regulations make clear its GLP regulations only apply to studies in support of a pesticide registration or tolerance (40 CFR 160.1(a), 160.3). In any event, non-compliance with the GLP regulations does not

automatically disqualify a study from EPA consideration but rather goes to reliability (40 CFR 160.17(a)). (As noted, Petitioners have made no claim that the ORD data is not reliable.).

*(v) Subissue: Was EPA's selection of a 4X children's safety factor consistent with EPA's approach to other carbamate pesticides?* Petitioners object that EPA was inconsistent in retaining a 4X children's safety factor for carbofuran given that EPA removed the children's safety factor for other carbamates. A hearing is not appropriate on this subissue because it presents a purely legal question. There is no dispute regarding the facts of EPA's decision in each case, the only question is whether EPA acted appropriately on carbofuran given its decision on the children's safety factor for other carbamate pesticides, such as carbaryl. The objection is denied because EPA's decisions in each case were consistent; EPA applied a different children's safety factor to carbofuran than to the other carbamate pesticides based on the different facts in each case. For example, the data showed that carbaryl differed significantly from carbofuran in terms of each chemical's relative sensitivity in juveniles with regard to brain and RBC AChE inhibition. For carbofuran, EPA concluded that RBC AChE inhibition in juveniles was more sensitive than brain AChE inhibition in juveniles by a factor of 4X. For carbaryl, the AChE inhibition in brain and RBC of juveniles was essentially equal.

*(vi) Subissue: Did EPA err in not using within-animal brain to RBC AChE inhibition comparisons to derive the children's safety factor?* EPA derived an alternate to the default 10X children's safety factor based on the ratio of RBC and brain AChE inhibition.

In their comments on the proposed rule, Petitioners criticized this approach, arguing that EPA should have compared the RBC and brain AChE inhibition levels at the same time in the same rat when these rats are exposed to carbofuran. Petitioners claimed to have done such an analysis and that the analysis showed that within rat inhibition levels in brain and RBC AChE were roughly equivalent. Although the results of the statistical analyses were summarized in the comments, the underlying analysis was not submitted. In the final tolerance revocation regulation, EPA extensively reviewed the "within animal" approach and rejected it as fundamentally flawed in several regards. Additionally, EPA noted that EPA's review of the Petitioners' suggested approach showed that it produced results, which are in fact consistent with EPA's conclusions. In their objections, Petitioners do not respond to EPA's rejection of the within animal approach in the final tolerance revocation rule either by explaining their disagreement with EPA's critique or proffering evidence to counter EPA's conclusion. Rather, Petitioners simply resubmitted essentially the same comments they provided on the proposed rule. Petitioners also again failed to submit the underlying analysis supporting their within animal calculations.

A hearing on this subissue is not appropriate for two reasons. First, Petitioners' repeated failure to submit the analysis supporting their claim reduces this objection to a mere allegation. Under EPA's regulations, hearings will not be granted on the basis of mere allegations. More importantly, Petitioners' objection on this subissue is irrelevant, and therefore immaterial, with regard to EPA's final tolerance revocation regulation because Petitioners ignored

EPA's extensive analysis of this subissue in the final rule and refiled their comments on the proposal as if EPA's determination in the final rule did not exist. The statute, however, requires that objections be filed on the final rule, not on the proposal. By ignoring the EPA's final rule on this subissue, Petitioners have failed to lodge a relevant objection. Both EPA and FDA precedent make clear that when the agency substantively responds to comments on the proposal, the commenter may only keep that issue alive in its objections by addressing the agency's substantive response. In other words, the final rule is the focal point for determining whether issues remain that must be resolved by the objection and hearing process. Any other approach relegates the notice-and-comment rulemaking stage of the revocation process to a meaningless exercise.

Petitioners' objections on this subissue are denied as irrelevant to the conclusions reached in the final rule. The final rule explains why Petitioners' arguments are without a basis, and Petitioners have failed to address that explanation. For essentially the same reasons, EPA denies the objection.

For essentially the same reasons, EPA denies the hearing request and objection designated above as *Objection/hearing request sub issue: Technical Flaws in EPA's statistical comparisons.* Petitioners' objection and hearing request on this subissue consist of mere reiteration of the comments submitted in response to the proposed tolerance revocation. The final rule explained the reasons that Petitioners' arguments are flawed, and the objections are denied for the same reasons.

*(vii) Subissue: Is EPA's approach to comparing brain and RBC AChE inhibition in juveniles due to carbofuran exposure scientifically valid?* Petitioners allege that EPA's approach to calculating the relative sensitivity between AChE inhibition in brain and RBC in juveniles is not scientifically valid. EPA derived the ratio of RBC and brain AChE inhibition using the data on administered dose (measured in terms of $BMD_{50}$) for PND11 animals. In addition, the Petitioners criticize EPA for incorrectly assuming that the relationship of the dose response curve between $BMD_{50}$s and $BMD_{10}$s is linear, which they claim overstates the potential differences. In support of the claim that EPA's approach overstates the differences, Petitioners argue that data suggests that $BMD_{50}$s for brain and RBC AChE inhibition for the carbamates tend to diverge more than the dose levels that cause the low levels of AChE inhibition used to select the PoD (*i.e.*, the $BMD_{10}$s), which demonstrates that at levels causing lower levels of inhibition, no safety factor is necessary. Petitioners' argument is that the 4X ratio EPA calculated based on the $BMD_{50}$ is unnecessarily protective, because the difference between brain and RBC at the doses causing lower levels of inhibition (*i.e.*, 10%), which are the levels at which EPA is regulating, would not be significant.

Petitioners' hearing request on this subissue is denied for two reasons. First, Petitioners proffered no evidence on any carbamate, much less carbofuran, in support of their claim that $BMD_{50}$s for the carbamates tend to diverge more than the $BMD_{10}$s or that the response curve between $BMD_{50}$s and $BMD_{10}$s is not linear. A hearing will not be granted on the basis of

mere allegations. Second, Petitioners' claims are immaterial because unless Petitioners can show what the relationship is between the response curves for $BMD_{50}$s and $BMD_{10}$s (an assertion they have not even made), a showing that EPA's assumption of linearity is incorrect can only force EPA to abandon the 4X children's safety factor in favor of the default 10X value.

The objection that EPA's modeling is scientifically invalid is denied. EPA's modeling has been repeatedly reviewed and approved by the SAP, including most recently with respect to the modeling of carbofuran's dose-response curves. There is no indication in the modeling that EPA's assumption of parallel dose-response curves overstates the difference, and given the absence of data supplied by Petitioners in support of this objection, the objection is denied.

*(viii) Subissue: Did EPA err by combining data from different toxicological studies in calculating the estimates of $BMD_{50}$s that serves as quantitative support for derivation of the 4X childrens' safety factor?* In its risk assessment, EPA relied on all of the valid data from the available studies to calculate the estimates that served as the PoD, and to calculate $BMD_{50}$s used in choosing the children's safety factor. In their comments on the proposed rule, Petitioners claimed that EPA's decision to combine data for different strains of rats, sexes, experiments, laboratories, dates, dose preparations, rat ages, and times between dosing and AChE measurement, is problematic, claiming that these differences in study design severely limit the validity of EPA's comparisons and caused EPA to overestimate the difference between brain and RBC AChE inhibition. EPA

responded to these comments in full during the rulemaking (74 FR 23052-23053; Ref. 85). Petitioners referenced their earlier comments in their objections, but presented no further evidence on any of these points. Nor in their objections and request for hearing did Petitioners address EPA's explanation set forth in the final rule.

A hearing is not appropriate on this subissue because Petitioners have not challenged the basis EPA asserted in the final rule for rejecting their concerns nor have they proffered any evidence that calls the substance of EPA's conclusions into question. A hearing is not warranted on the basis of mere denials or contentions, nor when the commenter simply reiterates comments raised in response to the proposed rule (40 CFR 178.32(b)(1) and (2)). Additionally, this hearing request is rejected for lack of materiality. If EPA abandoned its sophisticated analysis of multiple studies and datasets and simply followed the general approach laid out in its BMD policy, EPA would have chosen a significantly lower BMD dramatically raising EPA's risk estimates.

Petitioners' objection on this subissue is denied because Petitioners have not responded to the explanation EPA provided in the final rule supporting its meta-analysis of multiple studies. Consistent with Agency guidance, EPA believes that consideration of all available data is the scientifically more defensible approach, rather than the selective exclusion of reliable data. Petitioners' objection on this point is particularly weak given that their analysis also combines various data sets and only arrives at a higher estimate of the BMD by selectively excluding, without explanation, the

data most pertinent to assessing carbofuran's acute affects.

*b. Drinking Water Exposure Objection*—In large part, Petitioners' objections to EPA's assessment of carbofuran levels in drinking water are inextricably intertwined with their recently-proposed registration amendments which attempt to create a scheme whereby carbofuran use would be limited in individual watersheds. As explained above (see Unit VI.F.2.a), objections based on these recently-proposed registration amendments are irrelevant to EPA's determination in the final tolerance revocation rule. Nonetheless, in Unit VI.F, EPA exhaustively evaluated all of the arguments put forward in Petitioners' drinking water objection and explained why a hearing was not appropriate on any of these arguments and why, on the merits, the arguments were without basis. Below EPA has summarized its reasoning.

The first four subissues below pertain to EPA's assessment of the carbofuran groundwater exposure assessment and the last eight address the surface water assessment. In this regard, it is important to note that, in order to determine that a tolerance for a particular use will be safe, EPA must be able to determine that anticipated concentrations in both surface water and ground water resulting from that use will be safe.

*(i) Subissue: Did EPA err in relying on the results of the prospective ground water study (PGW) and historical monitoring to validate groundwater exposure estimate?* The Petitioners object that EPA should not have relied for validation on their PGW study or historical monitoring data. They argue that

these data no longer reflect current use patterns and that all areas like those seen in the PGW have now been removed from the carbofuran label.

A hearing is not appropriate on this subissue because the Petitioners have failed to proffer evidence, which would, if established, resolve a material issue in their favor. First, Petitioners fail to take into account the clear record evidence that EPA scaled the PGW modeling to reflect the lower current use rates. Second, Petitioners are simply incorrect to claim that EPA "validated" its quantitative groundwater assessment based on historic monitoring data that are not reflective of current application rates. The targeted monitoring data used for validation were based on application rates that are identical or lower than the current use rates. Third, the majority of Petitioners' evidence is untimely, and to the extent Petitioners' are claiming that the PGW and other targeted monitoring data are not reflective of FMC's June 29, 2009 proposed registration amendments, that claim is irrelevant to the current proceeding. Finally, Petitioners' evidentiary proffer on the PGW is internally contradictory given that Petitioners' own experts relied on the PGW to validate the modeling submitted in support of this objection.

The objection on this subissue is denied because timely evidence and reasoning submitted by Petitioners is contradictory, non-probative, or flatly contradicted by the record.

*(ii) Subissue: Does EPA's assessment of carbofuran levels in ground water account for all of FMC's label mitigation measures and "rely on unrealistic and overly conservative assumptions about potential concentrations"?* In this objection, the

Petitioners allege that maximum concentrations of carbofuran in groundwater are expected to be below 1.1 ppb, based on their proposed geographic restrictions and well setbacks. EPA believes Petitioners' objection and hearing request on this subissue is inextricably intertwined with FMC's recently-submitted FIFRA registration amendments and thus the objection is denied as irrelevant on that account.

Nonetheless, to the extent possible EPA has attempted to evaluate this objection based on the label mitigation measures submitted and adopted prior to issuance of the final tolerance revocation rule and ruled on it on that basis. EPA denies the objection and its associated hearing request because Petitioners have again failed to object to EPA's final rule. It is clear from the record that EPA's final rule and risk assessment did account for all of the risk mitigation measures submitted as part of the September 2008 comments. Petitioners have not raised any substantive challenge to the manner in which EPA's modeling addressed those measures. In addition, Petitioners' objections provide no further clarification as to what is meant by their claim that EPA's assessment relied on "unrealistic and overly conservative assumptions." Therefore, this objection, and the attendant hearing request, is denied based on Petitioners' failure to state with "particularity * * * the basis for the objection * * *."(40 CFR 178.25(a)(2)). As Petitioners raised similar allegations in their comments, EPA has assumed that they intended to incorporate all of the issues raised in the comments on the proposed rule. However, EPA addressed these assertions in the final rule. Because Petitioners have once again ignored the

explanations provided in the final rule, this objection and hearing request are denied as immaterial.

*(iii) Subissue: Is EPA's assessment of the levels of carbofuran in groundwater appropriate given the manner in which EPA assessed groundwater exposures in the NMC CRA?* Petitioners object that EPA's estimates in the final rule are inconsistent with the groundwater concentration estimates EPA developed for the NMC CRA. However, they do not identify any specific inconsistency, they simply make the general allegation. They allege that, by contrast, their assessment, which estimated maximum concentrations of 1.1 ppb, is consistent with the NMC CRA.

EPA denies the request for a hearing on this subissue because there is no disputed factual matter for resolution (*i.e.*, the manner in which EPA assessed groundwater exposure for carbofuran and for the NMCs is a matter of record); rather, the objection poses the legal question of whether it was appropriate for EPA to assess groundwater exposure for carbofuran and the NMCs in a different manner. Further, because Petitioners have not identified any specific inconsistency between the two groundwater exposure assessments, it constitutes nothing more than a mere allegation or denial. As EPA's regulations make clear, a mere "denial" of an EPA position is not sufficient to satisfy the standard for granting a hearing (40 CFR 178.32(b)(2)). Finally, the claim that their modeling is consistent with the NMC CRA does not justify a hearing on this question. As EPA explained in the final rule, the values estimated in the modeling conducted for the NMC CRA are greater than the 1.1 ppb level that FMC claims is the maximum

expected 1-in-10-year peak concentration. A hearing is not warranted where the claim is clearly contradicted by the record (40 CFR 178.32(b)(2)).

On the merits, Petitioners' objection is denied because the results of Petitioners' groundwater assessment are not consistent with the estimates developed for the NMC CRA. The NMC CRA examined carbofuran at two sites, northeast Florida and the Delmarva Peninsula. In Florida, concentrations were found to be below levels of concern because of high pH, but in Delmarva, both in corn and in melon scenarios EPA estimated that 90% of daily concentrations could be as high as 20.5 and 25.6 ppb, respectively. These values are far greater than the 1.1 ppb that Petitioners claim is the maximum expected 1-in-10-year peak concentration.

*(iv) Did EPA err in not using PCT data in assessing surface water exposure?* The Petitioners object to the assumption in the surface water assessments in the final rule that 100% of the crops in a watershed will be treated with carbofuran. The Petitioners argue that actual carbofuran sales data on a county basis from 2002-present demonstrate that the current carbofuran PCT is less than 4.25%. Using this PCT, and taking into account the recently submitted "no application buffers," the Petitioners allege that the modeling in Exhibit 15 demonstrates that carbofuran concentrations in surface water will not exceed 1.1 ppb, "which is below the level of concern." In support of this objection, the Petitioners reference county level sales data that were submitted to the Agency after the close of the comment period. They also reference the use tracking system proposed in their recent registration amendments (Exhibit 2) and the modeling

contained in Exhibit 15. Because this subissue is inextricably intertwined with Petitioners' recently-proposed FIFRA registration amendments, it is denied as irrelevant.

To the extent Petitioners' objection on this subissue is limited to EPA's refusal to use a 4% PCT in estimating drinking water concentrations in individual watersheds based on the information provided as part of their comments on the proposed rule, this objection and hearing request are also denied as immaterial. The Petitioners have failed to respond to EPA's explanation in the final rule that the information and methodology on which they relied to estimate a 4% PCT was fundamentally flawed, and to submit any evidence calling the basis of EPA's response into question (40 CFR 178.32(b)(3)). Additionally, the proffered evidence here is untimely. The sales data and methodology used to generate use estimates, as well as the modeling in Exhibit 15, were not submitted during the comment period on the proposed rule even though the information was clearly available to Petitioners (40 CFR 178.32(b)(2)).

Petitioners' objection on this subissue is denied because the proffered evidence is untimely and, even if considered, insufficient. Although EPA does use reliable data on pesticide usage in estimating exposure levels in food, this approach has limited applicability in drinking water assessments due to the differences in the sources of food and water for consumers. The food market in the United States is national in scope but the sources of drinking water are primarily local. Thus, while differences in the usage of pesticides across the country will average out in estimating pesticide exposure from food, such averaging is not applicable to

estimating pesticide exposure in drinking water—*i.e.*, a person's drinking water exposure is generally always from the same watershed. Moreover, the information that Petitioners submitted on PCT was not usage data—the type of information normally used in estimating PCT for food—but sales data. The link between sales data and the location of use is tenuous. Given that EPA lacks the information to allow EPA to generally use PCT information in estimating drinking water exposure, and the poor quality of information Petitioners submitted on usage (i.e. county-level sales data), EPA concludes it could not make an exposure estimate on carbofuran in drinking water with sufficient confidence to meet the FFDCA's reasonable certainty of no harm standard.

*(v) Subissue: Do the results of FMC surface water modeling establish that carbofuran levels will not exceed 1.1 ppb?* The Petitioners claim that the prior surface water assessments submitted to the Agency and a new assessment incorporating FMC's newly-proposed FIFRA registration amendments demonstrate that carbofuran concentrations in surface water are not expected to exceed 1.1 ppb. Because this subissue is inextricably intertwined with Petitioners' recently-proposed FIFRA registration amendments, it is denied as irrelevant. Nonetheless, EPA has carefully evaluated all of Petitioners' allegation to determine if any of their claims meet the standard for a hearing or are otherwise meritorious.

A hearing is also denied on this sub-issue because Petitioners' objection on this subissue is irrelevant, and therefore immaterial, with regard to EPA's final tolerance revocation regulation. Petitioners have not responded to EPA's extensive analysis of these

studies, which included an explanation for the Agency's conclusion that they were significantly flawed, presented in the final rule. The statute, however, requires that objections be filed on the final rule not the proposal. By ignoring EPA's final rule on this subissue, Petitioners have failed to lodge a relevant objection. Both EPA and FDA precedent make clear that when the agency substantively responds to comments on the proposal, the commenter may only keep that issue alive in its objections by addressing the agency's substantive response (40 CFR 178.32(b)(3)). Similarly, the Petitioners' new assessment directly relies on FMC's newly-proposed FIFRA registration amendments and is thus irrelevant to this proceeding. Their new assessment is also untimely in that it primarily appears to be a fuller description of Petitioners' National CWS Assessment, which was described, but not provided as part of their comments on the proposed rule (40 CFR 178.32(b)(2)).

EPA has outlined the substantial flaws in the previously-submitted assessments in the final tolerance revocation rule and in Unit VI.F, above. For the all the reasons cited therein, this objection is denied.

*(vi) Did EPA inappropriately rely on NAWQA monitoring data in assessing carbofuran levels in surface water?* The Petitioners object to EPA's discussion in the final rule of the high concentrations detected in Zollner Creek in Oregon and claim that EPA inappropriately relied on NAWQA monitoring data in estimating surface water exposure levels of carbofuran. A hearing on this issue is denied because there are no material factual issues in dispute. The extent to which EPA discussed the Zollner Creek data as part of its discussion of monitoring results from all

other NAWQA sites, SDWA post-treatment monitoring, and the results of field studies is clear on the record. The record is also clear regarding the degree of reliance EPA placed on monitoring data in estimating carbofuran levels in surface water. The objection on this subissue is denied because it was reasonable for EPA to consider NAWQA data in assessing the likelihood that carbofuran residues may be present in surface water. Moreover, the record is clear that, even though EPA considered the NAWQA data, it placed primary emphasis on the carbofuran levels detected in post-treatment SDWA monitoring.

*(vii) Should EPA consider FMC's newly-proposed terms of registration for carbofuran?* The objection is denied because it is based on FMC's newly proposed revisions to its carbofuran registration that were submitted after publication of the final tolerance revocation rule and is thus irrelevant to this proceeding. An additional ground for denial of this objection and hearing request is that Petitioners proferred no evidence to support their allegation that these proposed requirements would be effective in limiting carbofuran exposure to the extent claimed

*(viii) Should EPA have used the NMC CRA surface water estimates in assessing exposure to carbofuran in surface water?* Petitioners object to EPA's surface water exposure estimates on the ground that they are inconsistent with the estimates EPA developed for purposes of the NMC CRA. This hearing request is denied because there are no factual matters in dispute; rather, the only question is a legal one of whether it was inappropriate for EPA to use different approaches to assessing surface water exposure for the carbofuran surface water assessment

and the cumulative assessment of surface water exposure for NMCs (40 CFR 178.32(b)(1)). In addition, this issue was raised in Petitioners' comments on the proposed revocation. In the final revocation, EPA explained how the substantial differences between a cumulative risk assessment for a class of pesticides and a risk assessment for a single pesticide necessitate different approaches. Petitioners have not challenged the substance of EPA's response to their comments or submitted evidence that calls the substance of EPA's final rule conclusions into question, and the objection and associated hearing request is therefore immaterial (40 CFR 178.32(b)(3)). Finally, on multiple grounds, Petitioners' evidentiary proffer is insufficient to support a conclusion that there is a reasonable possibility that the issue could be resolved in their favor. Petitioners' objection on this subissue is denied for essentially the same reasons explained in the final tolerance revocation.

*(ix) Has EPA taken natural surface water pH conditions into account?* The Petitioners contend that the PCT levels guaranteed by the recently proposed use tracking system, along with natural surface water pH conditions in the areas included under the revised label will ensure that potential exposures are de minimis. Because this objection is inextricably intertwined with FMC's newly-proposed FIFRA registration amendments, it is denied as irrelevant to this proceeding.

Even assuming Petitioners' allegation concerning soil pH can be separated from the proposed registration amendments, Petitioners' claims are insufficient to justify the action urged (40 CFR 178.32(b)(3)). Petitioners admit that their pH analyses

explicitly only capture 95% of surface waters. Because EPA cannot ignore the other 5% of surface water, this information, even if established, would provide an insufficient basis on which EPA could reasonably conclude that the drinking water exposures would be "safe." Additionally, the proffered evidence for this objection is untimely because although the effects of pH were clearly discussed in the proposed rule, Petitioners' claim and the analyses supporting it were not submitted during the comment period.

For the same reasons, the Petitioners' objection is denied.

*(x) Has EPA taken the effect of existing drinking water treatment systems into account?* The Petitioners contend that, in the areas where carbofuran use is allowed under revised labels, the majority of the total population is protected from carbofuran by water treatment systems and that the rest of the population is protected by Petitioners' newly-proposed FIFRA registration amendments. Because this objection is inextricably intertwined with FMC's newly-proposed FIFRA registration amendments, it is denied as irrelevant to this proceeding.

Separating out the allegations that are independent from the new registration amendments, EPA denies this hearing request on the grounds that Petitioners' claims are insufficient to justify the action urged (40 CFR 178.32(b)(3)) in that they would fail to justify a conclusion that the carbofuran tolerances are safe. The fact that the majority of people are protected is irrelevant if major identifiable subpopulations are not. Further, both the objection and the proffered evidence are untimely because Petitioners' claims and analyses supporting them were not submitted during the

comment period. For the same reasons, this objection is denied.

*c. Recovery Time Objection—(i) Subissue: Has EPA overstated risk through its approach to considering recovery time to the effects of carbofuran?* For carbofuran, EPA estimated acute dietary exposure for the acute risk assessment by summing exposure over a 24-hour period. Because humans are likely to recover in a relatively short time period from any single carbofuran exposure, EPA also undertook a more sophisticated exposure assessment that took recovery time into effect. This more sophisticated analysis was not substituted for the 24-hour assessment approach but rather was used to evaluate whether the 24-hour approach substantially overstated risk. The reason for not simply adopting the assessment incorporating recovery time was based on concerns that other aspects of its exposure model tend to understate exposure. If the assessment using recovery time had suggested that carbofuran risks may be acceptable, EPA would have further examined how exposure should be assessed. However, because both the assessment based on 24-hour exposure and the one incorporating recovery time showed carbofuran exposures significantly exceed the safe level, EPA concluded that its exposure assessment was reasonable. Further supporting this conclusion was the fact that various other analyses showed that a single eating occasion could result in excessive risk to infants. Petitioners have objected to this approach claiming that recovery time should be included in EPA's "primary" risk assessment.

EPA is denying this hearing request on two grounds. First, the objection fails to present a disputed

issue of material fact because EPA did incorporate recovery time into its analysis. Rather, Petitioners' only challenge is to whether EPA should have only presented risk estimates that accounted for recovery. This is a policy issue, and hearings are not appropriate on such (40 CFR 178.32(b)(1)).

Second, the fact that EPA relied on 24-hour aggregate exposures in addition to analyses that accounted for recovery is not material, because even though accounting for recovery resulted in a 2-3X reduction in exposure estimates, many of EPA's estimates for aggregate exposures ranged between 2700% aPAD and 9400% aPAD for infants. Accounting for recovery does not, therefore, demonstrate that aggregate exposures will be safe for infants. Of greater significance in this regard is EPA's finding that infants are at risk from a single exposure. Recovery is only relevant, by definition, where the risk is derived from multiple exposures over time.

Petitioners' objection to EPA's policy decision to present acute risks in terms of 24 hours of exposure is denied because EPA's policy approach here is reasonable. For the reasons explained in Unit VI.G, there are several factors that may cause EPA's exposure/risk model to either understate or overstate exposure/risk. It is unreasonable to present risks only incorporating factors that tend to reduce exposure/risk estimates (e.g., recovery time), as Petitioners suggest. EPA's approach of evaluating the impact that these factors may have on the risk assessment is an appropriate method of taking all relevant factors into account.

*(ii) Subissue: Did EPA err in calculating carbofuran half-lives?* In the proposed rule, EPA used

half-lives of 150 minutes and 300 minutes, based on calculations derived for the NMC CRA. In the final rule, EPA calculated half-lives specific to carbofuran to ensure that its analyses accurately reflected carbofuran's risk. Petitioners contend that EPA's calculation of carbofuran half-lives of 186 minutes and 426 minutes were flawed, and that the data instead support the use of a 150-minute half-life.

Petitioners' hearing requests on this subissue are denied for two reasons. First, Petitioners have not provided the underlying analyses conducted in support of their claims that the appropriate half-life for carbofuran is 150 minutes, rather than the 186 or 426 minutes that EPA calculated. Petitioners' evidentiary proffer thus consists of no more than mere allegations and denials. Hearings will not be granted on this basis (40 CFR 178.32(b)(2)).

Further, the issue of the appropriate half-lives for carbofuran is not material. Petitioners have proffered no evidence to show that reliance on a 150-minute half-life rather than a 186-minute half-life would make a significant difference to their estimates. By contrast, in the risk assessment supporting the final rule, EPA's estimates show that the use of a 150-minute or 186-minute half-life makes little or no difference. In addition, EPA's final risk assessment found that infants are at risk from a single exposure. Recovery is only relevant, by definition, where the risk is derived from multiple exposures over time.

EPA denies Petitioners' objection on this subissue because the evidence submitted fails to establish their allegations, or to rebut the data and analyses discussed in the final rule.

*d. Human Study Objection—Issue: Did EPA reasonably conclude that a human toxicity study with carbofuran was barred from EPA consideration by the Human Research Rule?* In conducting its dietary risk assessment for carbofuran, EPA relied on toxicity data conducted with rats, and applied the default 10X interspecies factor to account for the potential uncertainty in extrapolating from animal data to humans. Petitioners object to the decision to use a 10X interspecies factor claiming that data from a human toxicity study (Arnold) provides a basis for reducing this factor to 3X. However, EPA has previously determined that the Arnold study lacks scientific validity and thus may not be considered by the Agency under EPA's Human Research rule. That decision was based on the advice of the HSRB, which found the Arnold study to constitute "poor science" (Ref. 38 at 11).

Although Petitioners have made a number of arguments in support of adopting a 3X interspecies factor, all of the arguments rely on consideration of the Arnold study. Thus, as a preliminary matter, Petitioners must show that a hearing is appropriate based exclusively on whether EPA erred in determining that the Arnold study cannot be considered under the Human Research rule or, that even if a hearing is not warranted, that EPA's decision under the Human Research rule was incorrect.

Petitioners have proffered no evidence that merits a hearing on EPA's application of the Human Research rule to the Arnold study. As an evidentiary proffer, Petitioners claim (1) that review of the Arnold study under the Human Research rule was too narrow in that it did not consider the Arnold study in light of the

animal data; (2) that insufficient weight was given prior independent reports on the value of the Arnold study; (3) that the "technical" concerns raised by the HSRB are addressed by "the data within the study" and that these "technical" deficiencies do not render the Arnold study unreliable. The first proffer is not material because the availability of animal data does not address the validity of the Arnold human study. At bottom, this issue involves a challenge to the policy underlying the Human Research rule that allows only limited consideration of human toxicity studies. A hearing is not appropriate on such a policy issue, nor on the Human Research rule itself. Petitioners' second proffer is a legal/policy question regarding the weight to be accorded to existing peer review reports. No hearing is required on such issues. To the extent the third proffer even constitutes a proffer of "evidence," it fails because it is nothing more than a mere allegation. Petitioners have supplied no information as to how the HSRB's "technical" concerns are resolved by the study itself.

Viewed on their merits, these claims do not convince EPA that it erred in determining that the Arnold study did not meet the Human Research rule because it lacked scientific validity. EPA concluded, based on the advice of the HSRB, that, because the Arnold study had an extremely small sample size (2 persons per dose) and highly variable measurement of RBC and plasma AChE, it had no scientific value. The claim by Petitioners that somehow the Arnold study could be rehabilitated by considering it in the context of carbofuran animal data misunderstands the issue. The question under the Human Research rule is whether the human study at issue is scientifically valid.

Here, EPA found the Arnold study to be flawed at its core. Animal data on carbofuran are simply irrelevant to the problems with sample size and AChE measurement in the Arnold study. As to the earlier reports on the Arnold study, Petitioners have provided no reason as to why these should outweigh the HSRB's conclusion concerning whether the Arnold study met the Human Research rule standard. The earlier reports were completed well before the Human Research rule was promulgated and thus could not have addressed the rule's requirements. Further, the earlier reports identified the same defects, but concluded that the Arnold's study's flaws could be addressed by the use of additional safety factors—an option not available under the Human Research rule. In such circumstances, it was reasonable for EPA to give primary weight to the HSRB findings. Petitioners' claim that the HSRB only identified "technical" problems with the Arnold study and that the study itself addresses the HSRB's concerns is without basis. The flaws in the Arnold study are not technical but fundamental, and cannot be explained away. Finally, Petitioners' allegations that EPA hampered the HSRB's consideration of the prior peer review reports and that EPA's recusal decision was somehow improper are contradicted by the record. Accordingly, the objection is denied.

*e. Import Tolerance Objection—Issue: Did EPA err by failing to retain the carbofuran tolerances that apply solely to imported food.* Whether EPA had some type of independent duty to retain carbofuran tolerances for the imported foods bananas, rice, coffee, and sugarcane despite its finding that aggregate exposure to carbofuran is unsafe, is a legal question.

Hearings are not held on legal issues. Having found that aggregate exposure to carbofuran is unsafe, EPA was clearly warranted, if not required, to revoke all tolerances. For the policy reasons identified above, (see Unit VI.I), when aggregate risk to a pesticide is unsafe, EPA defers to interested parties to decide in the first instance what tolerances, if any, they wish to retain. Although explicitly invited to do so, no person submitted a comment on the proposed revocation that identified the import tolerances as a subset of tolerances that were asserted to be safe, and that the commenter wished to retain. Accordingly, this objection is denied.

*K. Conclusion*

For all of the reasons set forth above, EPA denies the Petitioners' objections and their requests for a hearing on those objections.

**VII. Regulatory Assessment Requirements**

As indicated previously, this action announces the Agency's final order regarding objections filed under section 408 of FFDCA. As such, this action is an adjudication and not a rule. The regulatory assessment requirements imposed on rulemaking do not, therefore, apply to this action.

**VIII. Submission to Congress and the Comptroller General**

The Congressional Review Act, (5 U.S.C. 801 *et seq.*), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, does not apply because this action is not a rule for purposes of 5 U.S.C. 804(3).

**IX. References**

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74 Fed. Reg. 23,046
Friday, May 15, 2009

ENVIRONMENTAL PROTECTION AGENCY
**40 CFR Part 180**
**[EPA-HQ-OPP-2005-0162; FRL-8413-3]**
**Carbofuran; Final Tolerance Revocations**
**AGENCY:** Environmental Protection Agency (EPA).
**ACTION:** Final rule.

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**SUMMARY:** EPA is revoking all tolerances for carbofuran. The Agency has determined that the risk from aggregate exposure from the use of carbofuran does not meet the safety standard of section 408(b)(2) of the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This final rule is effective August 13, 2009. Written objections, requests for a hearing, or requests for a stay identified by the docket identification (ID) number EPA-HQ-OPP-2005-0162 must be received on or before July 14, 2009, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the SUPPLEMENTARY INFORMATION).

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## II. Introduction

### *A. What Action Is the Agency Taking?*

EPA is revoking all of the existing tolerances for residues of carbofuran. Currently, tolerances have been established on the following crops: Alfalfa, forage; alfalfa, hay; artichoke, globe; banana; barley, grain; barley, straw; beet, sugar roots; beet, sugar tops; coffee

bean, green; corn, forage; corn, grain (including popcorn); corn, stover; corn, sweet, kernel plus cob; cotton, undelinted seed; cranberry; cucumber; grape; grape raisin; grape, raisin, waste; melon; milk; oat, grain; oat, straw; pepper; potato; pumpkin; rice, grain; rice, straw; sorghum, forage; sorghum, grain grain; sorghum, grain, stover; strawberry; soybean, forage; soybean, hay; squash; sugarcane, cane; sunflower, seed; wheat, grain; wheat, straw.

As discussed at greater length in Unit VII., on September 29, 2008, the sole registrant of carbofuran pesticide products, FMC Corporation requested that EPA cancel certain registrations. Consistent with the request, the registrant indicated that it no longer seeks to maintain the tolerances associated with the domestic use of carbofuran on the eliminated crops, and therefore no longer opposes the revocation of those tolerances. No other commenter indicated any interest in maintaining these tolerances. EPA is therefore revoking the tolerances associated with those domestic uses on two separate grounds. The first is that the tolerances will no longer be necessary because the registrations for these uses have been canceled (74 FR 11551, March 18, 2009) (FRL-8403-6). The tolerances that EPA is revoking on this basis are: Alfalfa, forage; alfalfa, hay; artichoke, globe; barley, grain; barley, straw; beet, sugar roots; beet, sugar tops; corn, fresh (including sweet); cotton, undelinted seed; cranberry; cucumber; grape; grape raisin; grape, raisin, waste; melon; oat, grain; oat, straw; pepper; rice, straw; sorghum, forage; sorghum, grain grain; sorghum, grain, stover; strawberry; soybean, forage; soybean, hay; squash; wheat, grain; and wheat, straw. The second basis is that EPA also finds, that as outlined in its July

31, 2008 proposed rule, revocation of these tolerances is warranted on the grounds that aggregate exposure to residues from these tolerances do not meet the safety standard of section 408(b)(2) of the FFDCA. The Agency is therefore revoking tolerances for these crops because aggregate dietary exposure to these residues of carbofuran, including all anticipated dietary exposures and all other exposures for which there is reliable information, is not safe.

The remaining tolerances the commenters seek to retain are: Banana; coffee bean; corn, forage; corn, grain; corn, stover; milk; potato; pumpkin; rice, grain; sugarcane, cane; and sun-flower, seed. EPA has determined that aggregate exposure to carbofuran greater than 0.000075 milligrams/kilogram/day (mg/kg/day) (*i.e.*, greater than the acute Population Adjusted Dose (aPAD)) does not meet the safety standard of section 408(b)(2) of the FFDCA. For the 11 remaining tolerances, based on the contribution from food alone, exposure levels are below EPA's level of concern. At the 99.9th percentile of exposure, aggregate carbofuran dietary exposure from food alone was estimated to range between 0.000020 mg/kg/day for children 6 to 12 years old (29% of the aPAD) and 0.000058 mg/kg/day (78% of the aPAD) for children 1 to 2 years old, the population subgroup with the highest estimated dietary exposure. However, EPA's analyses show that those individuals—both adults and children—who receive their drinking water from sources vulnerable to carbofuran contamination are exposed to carbofuran levels that exceed EPA's level of concern—in some cases by orders of magnitude. This primarily includes those populations consuming drinking water from ground water from shallow wells

in acidic aquifers overlaid with sandy soils that have had crops treated with carbofuran. Aggregate exposures from food and from drinking water derived from ground water in vulnerable areas (*e.g.*, from shallow wells associated with sandy soils and acidic aquifers) result in significant estimated accidences. The estimates for aggregate food and ground water exposure from such sources range between 780% of the aPAD for adults over 50 years, to 9,400% of the aPAD for infants. Similarly, EPA analyses show substantial exceedances for those populations that obtain their drinking water from reservoirs (*i.e.*, surface water) located in small agricultural watersheds, prone to runoff, and predominated by crops that are treated with carbofuran, even though there is more uncertainty associated with these exposure estimates. For example, estimated aggregate exposures from food and drinking water derived from surface water, based on corn use in Nebraska, range between 330% of the aPAD for youths 13 to 19 years old and 3,900% of the aPAD for infants.

Every analysis EPA has performed has shown that estimated exposures from drinking water from each remaining domestic use significantly exceed EPA's level of concern for children. Accordingly, aggregate exposures from food and water significantly exceed safe levels. Although the magnitude of the exceedance varies depending on the level of conservatism in the assessment, the fact that in each case aggregate exposures to residues of carbofuran fail to meet the FFDCA section 408(b)(2) safety standard, including where EPA relied on highly refined estimates of risk, using all relevant data and methods, strongly

corroborates EPA's conclusion that aggregate exposures to residues of carbofuran are not safe.

*B. Overview of Final Rule*

EPA's final rule preamble is organized primarily into two sections. Following a brief summary of the July 31, 2008 proposed rule, EPA summarizes the major comments received on the proposed rule, along with the Agency's responses in Unit VII. Because EPA only presents a summary of all of the comments received, readers are encouraged to also consult EPA's Response to Comments Documents, found in the docket for today's action (Refs. 111, 112, 113). These documents contain EPA's complete responses to all of the significant comments received on this rulemaking, and therefore will contain a more detailed explanation on many of the issues presented in Unit VII.

Unit VIII. presents the results of EPA's analyses of carbofuran's dietary risks. This Unit generally describes the bases for the Agency's conclusions that carbofuran presents unacceptable dietary risks to children. Readers are also encouraged to consult EPA's underlying risk assessment support documents, identified in the References section, and contained in the docket for today's action, for a more detailed presentation of EPA's scientific analyses.

Each of these units is generally organized consistent with the structure of a risk assessment. Each unit begins with a discussion of carbofuran's toxicity, and EPA's hazard identification, including a discussion of the issues surrounding the selection of the children's safety factor EPA has applied to this chemical. EPA then discusses issues relating to carbofuran's exposures from food and drinking water. The final section of each unit relates to EPA's

conclusions regarding the risks from carbofuran's aggregate (*i.e.*, food + water) exposures.

*C. What Is the Agency's Authority for Taking This Action?*

EPA is taking this action, pursuant to the authority in FFDCA sections 408(b)(1)(b), 408(b)(2)(A), and 408(e)(1)(A). 21 U.S.C. 346a(b)(1)(b), (b)(2)(A), (e)(1)(A).

* * *

Several commenters criticize the Agency for the assumption that 100% of the cropped area in a watershed is treated. These commenters claim that actual carbofuran sales data on a county basis confirm that the actual carbofuran PCT is less that 5%, with most PCTs less than 1%. The commenters claim that these county level sales data either were provided to EPA as part of reports prepared by their consultants, or would be provided to EPA. They further claim that "how these data were analyzed, interpreted, and applied" was provided to EPA in a report on best management practices.

While the Agency typically uses PCT in developing estimates of pesticide residues in food, this is entirely different than developing estimates of the percent of a watershed that is treated for purposes of estimating drinking water exposures. Food is generally randomly distributed across the nation without regard to where it is grown. This tends to even out any PCT variations that may arise on local levels. By contrast, the source of water consumption (and consequently exposure) is localized, either in a private well or a community water system. The PCT in any watershed will therefore

directly impact the residues to which people living in that watershed will be exposed.

For this reason, among others, for drinking water exposure estimation, the Agency assumes that 100% of the cropped area (or 100% PCT) is treated. EPA also makes this assumption due to the large uncertainties in the actual PCT on a watershed-by-watershed basis. EPA developed an extensive discussion of the uncertainties in PCT and how they impact drinking water exposure assessment in its proposed rule (73 FR 44834) and in a background document provided to the SAP considering the draft carbofuran NOIC (Ref. 59). Because usage is often not evenly distributed across the landscape, due to differences in factors like pest pressure, local consultant recommendations and weather, it may be much higher in some areas. Further, temporal uncertainties can result in changes in use that might be driven by weather, changes in insect resistance over time, and changes in agronomic practices. To date, methods that account for this uncertainty, given the nature of the available data, have not been developed. Consequently, EPA cannot accurately estimate a drinking-water watershed scale PCT that, when used in a quantitative risk assessment on a national or regional basis, standing alone, provides the necessary level of certainty to allow the Agency to confidently conclude that exposures will meet the FFDCA 408 safety standard.

In most cases, EPA agrees that it is unlikely that 100% of the crop will be treated in most watersheds, particularly in larger watersheds. However, for small watersheds, it is reasonable to assume that an extremely high percentage of the crops in the watershed may be treated.

Moreover, EPA has an obligation to evaluate all legally permitted use practices under the label, and to ensure that all such use meets the requisite statutory standards, not simply to base its decisions on the practices the majority might typically use. The September 2008 proposed label imposes no restriction on the application of carbofuran related to whether a particular percent of the watershed has been treated. Thus, even with the restrictions on FMC's September 2008 labels, it remains legally permissible for 100% of the watershed to be treated with carbofuran.

Nor is EPA aware of an enforceable mechanism to ensure that farmers applying pesticide to their individual fields will have the ability to determine whether a particular percentage of the watershed has been treated. There are significant practical difficulties inherent in implementing such label directions, as they force individual growers to have continual knowledge of the variances of the behavior of other farmers across the entire watershed. While for small watersheds that involve only one or two farms it might be feasible for neighbors to coordinate applications with respect to adjacent fields, for larger watersheds, the practical difficulties increase significantly.

However, in the proposed rule, EPA conducted a sensitivity analysis to explore the impact of PCT assumption on dietary risk using an assumed 10% PCT, a figure proposed previously by FMC (73 FR 48864). The results of that analysis demonstrated that even at these low percentages, which may significantly underestimate exposures, particularly in small watersheds, carbofuran exposures from drinking water contribute significantly to children's dietary risks. EPA

conducted a similar sensitivity analysis for this final rule, discussed below in Unit VIII.E.3., which demonstrates that even assuming that a low percentage of a watershed is treated, exposures will be unsafe for infants.

FMC has submitted three assessments that relied in part on what they refer to as "county-level usage data" (Refs. 36, 96, and 120). The description that EPA has been able to piece together from the registrant's various submissions indicates that the original source of the "county-level usage data" is sales data, apparently collected at the distributor level. FMC claims to have augmented these sales data in an unspecified manner, by incorporating information from the distributor, which FMC used to allocate carbofuran usage at the county level. FMC has provided maps representing county level and watershed-scale use estimates, but has not provided the actual usage estimates in any clearly understandable format. Nor, as of the close of the comment period, has any commenter provided either the "actual sales data" FMC used to develop these estimates, or the methods used to estimate county level usage from the sales data. FMC has provided only a limited description of how these data were collected and no description of how they were actually analyzed or validated; what FMC characterizes as "careful and proven techniques to capture this data" were not described. The method FMC used to attribute carbofuran sales to counties was not described. In the absence of the data or analyses described above, EPA is unable to verify or evaluate the results of any analyses that rely on these data and can reach no conclusion on its validity or utility.

The Agency agrees that county-level use data would be useful in generating reasonable estimates of PCT that could be used in drinking water assessments. However, as discussed in the previous responses, FMC has only provided county-level use estimates (not the underlying data nor the analyses that presumably are the basis for the estimates) for Illinois; county-level estimates to support other risk assessments have not been submitted by FMC as of the end of the comment period. The underlying sales data (*i.e.*, measurements) used to make the county-level estimates and the methods FMC used to estimate county level use from them have also not been submitted. FMC has provided limited characterization of the source data, noting that these data were derived from FMC billings and "EDI data", which they did not define, and that the sales data had been adjusted to reflect different use patterns and by removing use for patterns which they no longer support (*e.g.*, alfalfa). However, FMC did not provide adequate details on the methodology they used to make these adjustments.

A major problem with the method FMC seemingly used is that it does not appear to account for uncertainties due to variation in time and space and the potential for use to be locally concentrated due to pest pressures. The method FMC summarily describes as having been used to allocate county-level usage estimates to watersheds appears to be similar to a method that has been used by others for calculating "best-estimate" county-level PCT (Ref. 95) to map nation-scale pesticide usage. However, these methods are not appropriate for calculating PCTs for surface drinking water sources or watersheds that drain to CWSs, because they do not adequately account for the

uncertainty in the data at the appropriate spatial scale. This methodology produces an estimate that is a measure of central tendency and, as such, roughly half the estimated values will underestimate the PCT. Furthermore, because, pesticide use varies from year to year, and can in some cases be patchy, with high levels of use in small areas and little use in most areas, the underestimates of PCT can be substantial in small watersheds. As previously noted, methods for calculating PCT that account for these uncertainties have not been developed.

Several commenters allege that carbofuran use will not concentrate in areas due to pest pressure. One commenter criticizes EPA for failing to support its conclusion that the pest pressure and infestation patterns could result in concentrated usage that could occur within vulnerable watersheds, and claims that EPA ignored the county-level sales data provided by the registrant which can be used both to determine whether carbofuran usage is evenly dispersed or locally clustered (an assessment [FMC's contractor] expressly undertook) and the probability of concentrated usage within vulnerable watersheds.

Two commenters claim that, because "more than 60% of the total corn acreage is made up of rootworm resistant GMO corn, which vary rarely requires treatment," and the remaining acreage "is refugia acreage for GMO fields which is widely distributed geographically," it is a "virtual impossibility" that all corn acreage in a particular watershed will require a rescue treatment in any given year. Another commenter made similar allegations for sunflower acreage. The commenter claims that "[s]unflowers are a specialty crop that is only grown on a small

proportion of agricultural acreage generally, particularly in states where carbofuran is used (*i.e.*, Nebraska, Colorado, Kansas, and Texas)." According to the commenter, the available data suggests that sunflowers are only used on 25% of total cropped area, and that carbofuran is not used on all of these acres. As further support for this point, another commenter cites to the sunflower PCAs they calculated for Nebraska, Kansas, Colorado, and Texas," which they claim is 2.12%.

The Agency agrees that the true PCT is not likely to be 100%. However, as discussed in several places throughout this preamble, the Agency is certain that PCT is higher in some cases than values calculated by the commenter. The degree of spatial correlation, however, is unknown, and thus is a major uncertainty. FMC's own analysis of carbofuran use in watersheds in Indiana suggests that carbofuran use is indeed localized, as carbofuran use was found in watersheds of only 12 of the 35 community water supplies that they considered in the state (Ref. 120). This suggests that when pest pressure occurs it is not unreasonable to assume it will be localized. Other factors, such as market pressures, consultant recommendations, or local availability may also be driving disparate levels of use in different locations. Since there is no method to account for this uncertainty in estimating PCT, it cannot be estimated in this assessment with the degree of confidence consistent with the statutory requirement of a reasonable certainty of no harm.

The commenters raise several valid points that, taken together, reduce the probability that carbofuran usage will be concentrated over large geographical areas. However, the commenters failed to rebut EPA's

conclusion that carbofuran's use patterns could be concentrated in certain locations, such that a large percentage of a small watershed is treated. Their first observation that carbofuran is applied as a rescue treatment on 0.27% of all U.S. corn acreage is true at the national level. However, the commenters failed to note that there are regional differences in carbofuran use, and as the scale becomes smaller, one would expect these differences to become even greater, precisely because use of carbofuran is sporadic in both time and space. Large areas would not be treated, but smaller areas, such as some drinking water watersheds considered by EPA may have a significantly higher proportion of their acreage treated than compared to national estimates.

The commenters' point that control failures are more likely to occur on biotech corn refugia is valid and will tend to prevent treatment of large contiguous areas of corn. However, not all farmers plant biotech corn. Further, farmers who do grow biotech corn do not locate their refugia universally in one part of the field, and there is no requirement that farmers in contiguous fields coordinate the location of their respective refugia. Consequently, the possibility that several contiguous corn fields could be simultaneously treated in any given year is not precluded. It is worth noting in this context that the September 2008 labels do not restrict application to the refugia. Moreover, in those areas where carbofuran is applied aerially, such as Nebraska, it is frequently easier for applicators to treat an entire field, rather than restricting their application to only select portions of the field. This is particularly true in smaller fields. Finally, because usage is often not evenly distributed across the

landscape due to differences in factors like pest pressure, local consultant recommendations and weather, it may be much higher in some areas, and methods that account for this uncertainty, given the nature of the data, have not been developed.

EPA agrees that the 87% default PCA that has been used for EPA's drinking water exposure assessments is likely a conservative estimate of sunflower acreage in a watershed. However, EPA has not developed PCAs for specific crops other than for corn, wheat, and cotton, consistent with guidance provided by the FIFRA SAP (Ref. 38). Nevertheless, the sunflower growers' own estimate of sunflower PCAs range as high as 25%, which certainly cannot support a PCA of 2.12% as one of the commenters suggested.

One commenter complained that as part of the NMC CRA, EPA relied on actual "county-or multi-county level pesticide use information, based on agricultural chemical use surveys" to develop its estimates of potential exposure, rather than assuming 100% PCT." The commenter compares their surface water estimations to those developed by EPA for the NMC cumulative assessment, and claims that the two are consistent.

While it is true that in the NMC assessment, EPA used PCT numbers to estimate the cumulative exposure from the contamination of such pesticides in surface water, this was done in order to more accurately account for the likelihood of pesticide co-occurrence at a single drinking water facility. But this does not mean that use of PCT is appropriate in conducting an assessment of aggregate exposure from carbofuran residues in surface water. This difference

in approach between the assessment of a single chemical's aggregate exposure, and the assessment of the cumulative exposures from several chemicals, stems from the differences in the purpose and scope of the two assessments. These differences inevitably require the application of different methodologies.

In evaluating the acute risks associated with a single chemical's contamination of drinking water, EPA must consider all of the variations permitted under the label. Drinking water exposures are driven by uniquely local factors; not only is the source of drinking water local (i.e. a person drinks water from his or her local water system not from a combination of water systems from across the United States), but the likelihood and degree of contamination of any particular, local drinking water source, whether it is a reservoir or well, varies widely based on local conditions (e.g., from local pest pressures, weather). Given this local variability, EPA must evaluate how all of the practices permitted under the label will affect drinking water exposures, because all are legally allowed, and farmers may choose any of them based on their particular individual local conditions. This means that even if typically growers, on a national or regional basis, do not frequently use a particular practice, EPA must still evaluate whether aggregate exposures from that practice would be safe because the practice is legally permissible and may be used due to local conditions. Thus, for example, even if most growers tend to apply the chemical only to a portion of the field, or typically only apply one-half of the maximum application rate, EPA must determine whether use by all or some growers to the entire field or at the

maximum rate in a local watershed would result in unsafe drinking water concentrations.

By contrast, it is not feasible to conduct the identical analysis for a cumulative assessment of related chemicals. Since the potential combinations of variations in pesticide use practices for the group of pesticides to be assessed are essentially infinite, even with computer modeling it would be impossible to model or evaluate all of the combinations allowed under the labels. EPA therefore needed to narrow its evaluation of the possible combinations to those deemed "likely" to occur. In contrast to the single chemical assessment, a cumulative assessment is intended to develop a snapshot in time of what is likely occurring at the moment. Moreover, the purpose of a cumulative assessment is to identify major sources of risk that could potentially accrue due to the concurrent use of several pesticides that act through a common mechanism of toxicity. Thus, EPA is primarily interested in the subset of circumstances in which residues from such pesticides occur concurrently (or co-occur).

In addition, one of the important attributes of a cumulative risk assessment is that its scope and complexity can potentially lead to inflated estimates of risk due to compounding conservatisms, which would reduce the interpretability and ultimately the utility of the assessments. Because many data sets need to be combined, reducing the impact and likelihood of compounding conservative assumptions and over-estimation bias becomes very important in constructing a reasonable cumulative risk assessment.

When little or no information is available to inform potential sources of exposure, such as a reasonable or

maximum watershed scale PCT, it is both scientifically and legally reasonable for a single chemical assessment to incorporate conservative assumptions to reflect reasonable worst-case exposure estimates. But in a cumulative risk assessment, the incorporation of such conservative assumptions would imply multiple simultaneous reasonable worst-case exposure estimates for each individual chemical. This is so unlikely that the results would no longer represent even a reasonable worst-case estimate of the likely risks. Consequently, some of the conservative assumptions appropriately used in the single chemical risk assessments are not appropriate or reasonable for use in a cumulative risk assessment, and vice versa.

As a result, EPA chose in the NMC to work with those data that most closely reflect "representative" exposures, and developed "representative" estimates of PCT in regional watersheds. However, to be clear, the PCT values used in the NMC assessment do not represent estimates of 50% of watersheds, or even the "average" watershed; rather, they represent values that are expected to be as likely to be accurate as not, based on a random selection of watersheds. A comparable example is the statistic that the average American family has approximately 2 children; this may or may not be true for any individual family, but there is an equally good chance that it will be accurate for any randomly selected family, as that it will not be accurate. For the cumulative assessment, EPA is able accept this level of uncertainty in these estimates, precisely because it has confidence that aggregate exposures from the individual chemicals will be safe, based on the level of conservatism in the single chemical assessments. But given the statute's mandate

to ensure a "reasonable *certainty* of *no harm*," EPA could not rely on the approach used under the cumulative assessment in the absence of the more conservative single-chemical assessment that evaluates the full range of exposures permitted by the registration.

Nevertheless, as discussed in Unit VIII.E.3., in response to FMC's concerns EPA performed a sensitivity analysis of an exposure assessment using a PCT in the watershed to determine the extent to which some consideration of this factor could meaningfully affect the outcome of the risk assessment. The results suggest that, even at levels below 10% CT, exposures from drinking water derived from surface waters can contribute significantly to the aggregate dietary risks, particularly for infants and children. Accordingly, these assessments suggest that use of a reasonably conservative PCT estimate, even if one could be developed, would not meaningfully affect the carbofuran risk assessment, as aggregate exposures would still exceed 100% of the aPAD.

One commenter raised the concern that USGS monitoring found that concentrations of carbofuran in agricultural streams ranged from non-detect to 7 ppb (with a 95th percentile concentration of 0.044 ppb), noting that the monitoring strategy used by USGS for this program is likely to underestimate peak contamination levels (Ref. 114). The commenter argued that the USGS monitoring program is not designed to target waterways where carbofuran is in high use, or timed to coincide with predicted peak levels of pesticide runoff into waterways. Moreover, the frequency of sampling is normally weekly or bi-weekly, not enough to reliably sample the sporadic

peaks that are predicted to be associated with pesticide application days or heavy runoff following rains. This monitoring strategy is more likely to capture the trends in chronic pollutants, but miss peak events such as pesticide runoff following rain. The sampling strategy biases towards the null; that is, it is likely to underestimate contamination by missing peak events when they occur, but will not over-represent non-detects. The commenter alleged that the fact that these data show routine detections of carbofuran in streams from agricultural land use areas suggests that there are likely to be peak events that go undetected. These data further support EPA's decision to cancel carbofuran and support rejecting FMC's proposal to restrict its use only in a limited number of watersheds. Because carbofuran is detected in streams across the nation, FMC's spatially limited mitigation plan would fail to protect many waterways from contamination.

One commenter argued that FMC's proposal to restrict uses of carbofuran in the most vulnerable watersheds, to limit ground water contamination, would fail to provide adequate protection. The commenter noted "substantial monitoring data showing that carbofuran has been detected by the USGS in 10.4% of over 2,000 stream-water samples taken from 83 agricultural streams monitored from 1992-2001, demonstrating that it is a widespread water pollutant and that geographically limited mitigation measures are not likely to be adequately protective." (Ref. 114).

EPA agrees with the commenters that the risks of surface water contamination from carbofuran are significant, and that FMC's September 2008 labels do not mitigate the risks sufficiently.

* * *

a. *Exposure to carbofuran from drinking water derived from ground water sources.* Drinking water taken from shallow wells is highly vulnerable to contamination in areas where carbofuran is used around sandy, highly acidic soil, although sites that are less vulnerable (*e.g.*, deeper aquifer, higher organic matter) could still be prone to have concentrations exceeding acceptable exposures. The results of the ground water modeling simulations from the South-Central Wisconsin scenario show that the persistence of carbofuran in ground water is dependent on soil and water pH, and what might appear as relatively small variations in soil pH can have a significant impact on estimates of carbofuran in ground water. Estimated 1-in-10-year peak ground water concentrations at pH 7 are $1.6 \times 10^{-3}$ µg/L; however, the estimated 1-in-10-year peak ground water concentration at pH 6.5 is 16 µg/L, nearly 4 orders of magnitude greater. Because of carbofuran's sensitivity to pH, EPA has concerns that any given set of mitigation measures will not successfully protect ground water source drinking water. Data indicate that pH varies across an agricultural field, and also with depth (Ref. 64). In particular, the pH can be different in ground water than in the overlying soil. The upper bound of the carbofuran concentrations estimated by EPA at pH 6.5 is much greater than the concentrations FMC report in their comments.

In EPA's revised assessment, ground water concentrations were estimated for all remaining crops on carbofuran labels, and used two new Tier 2 scenarios. Based on a new corn scenario, representative of potentially vulnerable areas in the

upper Midwest, EPA estimated 1-in-10-year concentrations for ground water source drinking water of 16 to 1.6 x $10^{-3}$ µg/L, for pH 6.5 and 7, respectively. A potato scenario representing use in the Northwest estimated no measurable concentrations of carbofuran in ground water. Other remaining uses were modeled using a Tier 1 ground water model (Screening Concentration in-Groundwater) with estimated peak 90-day concentrations of 48 - 178 µg/L, depending on application rate. Well setback prohibitions of 50 feet were proposed on the new label for the flowable and granular formulations in select counties in Kentucky (seven counties), Louisiana (one county), Minnesota (one county), and Tennessee (one county). Analysis of the impact of these setbacks for the use on corn indicated that the setbacks would not reduce concentrations significantly at locations where exposure to carbofuran in ground water is of concern because at acid pHs, carbofuran does not degrade sufficiently during the travel time from the application site to the well to substantially reduce the concentration.

Exposure estimates for this assessment are drawn primarily from EPA's modeling. To conduct its modeling, EPA examined readily available data with respect to ground water and soil pH to evaluate the spatial variability of pH. Ground water pH values can span a wide range; this is especially true for shallow ground water systems, where local conditions can greatly affect the quality and characteristics of the water (higher or lower pHs compared to average values). Thus, average ground water pH values for a given area do not truly characterize the (temporal and especially spatial) heterogeneity common in most

areas. This can be seen by comparing differences in pH values between counties within a state, and noting that even within each county specific area, wells will consistently yield ground water with either above- or below-average pH values for that county. The ground water simulations reflect variability in pH by modeling carbofuran leaching in four different pH conditions (pH 5.25, 6.5, 7.0, and 8.7), representing the range in the Wisconsin aquifer system. The upper and lower bound of pH values that EPA chose for this assessment were measured values from the aquifer, and the remaining two values were chosen to reflect common pH values between the measured values.

The Idaho potato scenario is representative of areas where ground water is relatively deep and the soils have a relatively alkaline pH. The results from the Idaho potato ground water simulation estimated no measurable concentrations of carbofuran in ground water. This is consistent with EPA's findings above, as soils where potatoes are typically grown are more alkaline.

The results of EPA's revised corn modeling, based on a new scenario in Wisconsin, are consistent with the results of the PGW study developed by the registrant in Maryland in the early 1980s. Using higher use rates than currently permitted, the peak concentration measured in the PGW study was 65 ppb; when scaled to current use rates, the estimated peak concentration was 11 ppb. EPA's modeling is also consistent with a number of other targeted ground water studies conducted in the 1980s showing that high concentrations of carbofuran can occur in vulnerable areas; the results of these studies as well as the PGW study are summarized in References 17 and 84. For

example, a study in Manitoba, Canada assessed the movement of carbofuran into tile drains and ground water from the application of liquid carbofuran to potato and corn fields. The application rates ranged between 0.44-0.58 pounds a.i./acre, and the soils at the site included fine sand, loamy fine sand, and silt loam, with pH ranging between 6.5-8.3. Concentrations of carbofuran in ground water samples ranged between 0 (non-detect) and 158 ppb, with a mean of 40 ppb (Refs. 17 and 84).

While there have been additional ground water monitoring studies that included carbofuran as an analyte since that time, there has been no additional monitoring targeted to carbofuran use in areas where aquifers are vulnerable. However, as discussed in the next section, data compiled in 2002 by EPA's Office of Water show that carbofuran was detected in treated drinking water at a few locations. Based on samples collected from 12,531 ground water supplies in 16 states, carbofuran was found at one public ground water system at a concentration of greater than 7 ppb and in two ground water systems at concentrations greater than 4 ppb (measurements below this limit were not reported). An infant receiving these concentrations receive 220% of the aPAD or 130% aPAD, respectively, based on a single 8 ounce serving of water. As this monitoring was not targeted to carbofuran, the likelihood is low that these samples capture peak concentrations. Given the lack of targeted monitoring, EPA has primarily relied on modeling to develop estimates of carbofuran residues in ground water sources of drinking water.

Based on EPA's assessment, the maximum 1-in-10-year peak carbofuran concentrations in vulnerable

ground water for a single application on corn in Wisconsin, at a rate of 1 pound per acre were estimated to range from a low of less than 1 ppb based on a pH of 7 or higher, to a high of 16 ppb, based on a pH of 6.5[5]. Because the degradate, 3-hydroxycarbofuran, which is assumed to be of equal potency with the parent compound, was not measured in the PGW study, and key environmental fate data are not available to use in modeling, exposure was not estimated. Although the failure to include the degradate is expected to underestimate exposure to some degree, the extent to which it would contribute to exposure is unclear.

EPA compiled a distribution of estimated carbofuran concentrations in water based on these estimates that were used to generate probabilistic assessments of the potential exposures from drinking water derived from vulnerable ground water sources. The results of EPA's probabilistic assessments are represented below in Table 3. As discussed in the previous section, it is important to remember that the aPAD for carbofuran is quite low, hence, relatively low concentrations of carbofuran monitored or estimated in vulnerable ground water can have a significant impact on the aPAD utilized.

[Table 3 omitted]

While the registrant has attempted to address drinking water exposure from ground water sources by including additional restrictions on their September 2008 proposed labels, EPA's analyses show that these do not sufficiently reduce exposures to acceptable

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[5] Although higher estimates were generated at a pH of 5.25, use should be precluded in such sites based on the September 2008 labels.

levels. The proposed labels include well setback prohibitions at 50-foot-distances for the flowable and granular formulations in a select set of counties in Kentucky, Louisiana, Minnesota, and Tennessee. The impact of the well setbacks was modeled for the corn use using the approach developed for the NMC cumulative assessment (Ref. 107), resulting in reductions in concentrations that vary with pH (to account for degradation of the compound in subsurface flow from the application site to a private well down gradient). At acid pHs the slow degradation rate reduced the effectiveness of a 50-foot well setback at the well head (1-in-10-year peak concentration of 16 to 14 µg/L, a reduction factor of 0.73 at pH 6.5). Additional setback distances (100, and 300 ft) were evaluated using an aquifer pH of 6.5, resulting in reduction factors of 0.54 and 0.16, respectively. At alkaline pH, the 50-foot setback is effective, but concentrations at these sites are already low due to hydrolytic degradation occurring during recharge. These results suggest that a 50-foot well setback is less effective in low pH environments due to the persistence of carbofuran under these conditions.

In addition, the revised labels prohibit use throughout the Atlantic Coastal plain, and prohibit application to areas with soils greater than 90% sand and less than 1% organic matter, acidic soil and water conditions, and where shallow water tables predominate (*e.g.*, where ground water is less than 30 feet). While EPA agrees in principle that precluding use in sites vulnerable to leaching can mitigate the risks, and even presuming that the methodology used by FMC adequately identifies those sites, these criteria are not sufficient to prohibit use in all areas that could

reasonably be expected to be vulnerable to ground water contamination from carbofuran use. Based on carbofuran's characteristics, a diversity of soil conditions in the remaining proposed use area, and available monitoring data, there are valid scientific reasons to believe that additional soil and site characteristics could result in ground water contamination. For example, water table depth can vary with the time of the year, depending on such factors as the amount of rainfall that has occurred in the recent past, and how much irrigation has been applied to a field or removed from the aquifer. It is difficult to determine how the depth to the water table varies throughout fields, and the definition of a "shallow" water table on the September 2008 label is indeterminate (*e.g.*, less than 30 ft.). Furthermore, the vulnerability associated with depth varies with location, for example, deeper aquifers may be vulnerable in areas with greater precipitation and rapid recharge. The September 2008 label restrictions in no way addressed these less sensitive, but still vulnerable, sites (Refs. 94 and 111). Accordingly, EPA continues to believe that its assessment of drinking water from ground water sources based on current labels is a reasonable assessment of potential exposures to those portions of the population consuming drinking water from shallow wells in highly vulnerable areas.

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73 Fed. Reg. 44,864
Thursday, July 31, 2008

ENVIRONMENTAL PROTECTION AGENCY
**40 CFR Part 180**
**[EPA-HQ-OPP-2005-0162; FRL-8373-8]**
**Carbofuran; Proposed Tolerance Revocations**
**AGENCY:** Environmental Protection Agency (EPA).
ACTION: Proposed rule.

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**SUMMARY:** EPA is proposing to revoke all tolerances for carbofuran. The Agency has determined that the risk from aggregate exposure from the use of carbofuran does not meet the safety standard of section 408(b)(2) of the Federal Food, Drug, and Cosmetic Act (FFDCA). EPA is specifically soliciting comment on whether there is an interest in retaining any individual tolerance, or group of tolerances, and whether information exists to demonstrate that such tolerance(s) meet(s) the FFDCA section 408(b)(2) safety standard. EPA encourages interested parties to comment on the tolerance revocations proposed in this document and on the proposed time frame for tolerance revocation. Issues not raised during the comment period may not be raised as objections to the final rule, or in any other challenge to the final rule.

**DATES:** Comments must be received on or before September 29, 2008.

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2. *Exposure from water.* EPA may use field monitoring data and/or simulation water exposure models to generate pesticide concentration estimates in drinking water. Monitoring and modeling are both

important tools for estimating pesticide concentrations in water and can provide different types of information. Monitoring data can provide estimates of pesticide concentrations in water that are representative of the specific agricultural or residential pesticide practices in specific locations, under the environmental conditions associated with a sampling design (*i.e.*, the locations of sampling, the times of the year samples were taken, and the frequency by which samples were collected). Although monitoring data can provide a direct measure of the concentration of a pesticide in water, it does not always provide a reliable basis for estimating spatial and temporal variability in exposures because sampling may not occur in areas with the highest pesticide use, and/or when the pesticides are being used and/or at an appropriate sampling frequency to detect high concentrations of a pesticide that occur over the period of a day to several days.

Because of the limitations in most monitoring studies, EPA's standard approach is to use simulation water exposure models as the primary means to estimate pesticide exposure levels in drinking water. Modeling is a useful tool for characterizing vulnerable sites, and can be used to estimate peak pesticide water concentrations from infrequent, large rain events. EPA's computer models use detailed information on soil properties, crop characteristics, and weather patterns to estimate water concentrations in vulnerable locations where the pesticide could be used according to its label. (69 FR 30042, 30058-30065 (May 26, 2004)). These models calculate estimated water concentrations of pesticides using laboratory data that describe how fast the pesticide breaks down to other chemicals and how it moves in the environment at

these vulnerable locations. The modeling provides an estimate of pesticide concentrations in ground and surface water. Depending on the modeling algorithm (*e.g.*, surface water modeling scenarios), daily concentrations can be estimated continuously over long periods of time, and for places that are of most interest for any particular pesticide.

EPA relies on models it has developed for estimating pesticide concentrations in both surface water and ground water. Typically EPA uses a two-tiered approach to modeling pesticide concentrations in surface and ground water. If the first tier model suggests that pesticide levels in water may be unacceptably high, a more refined model is used as a second tier assessment. The second tier model is actually a combination of two models: the Pesticide Root Zone Model (PRZM) and the Exposure Analysis Model System (EXAMS).

A detailed description of the models routinely used for exposure assessment is available from the EPA OPP Water Models web site: *http://www.epa.gov/oppefed1/models/water/index.htm.* These models provide a means for EPA to estimate daily pesticide concentrations in surface water sources of drinking water (a reservoir) using local soil, site, hydrology, and weather characteristics along with pesticide application and agricultural management practices, and pesticide environmental fate and transport properties. Consistent with the recommendations of the FIFRA SAP, EPA also considers regional percent cropped area factors (PCA) which takes into account the potential extent of cropped areas that could be treated with pesticides in a particular area. The PRZM and EXAMS models used by EPA were developed by

EPA's Office of Research and Development (ORD), and are used by many international pesticide regulatory agencies to estimate pesticide exposure in surface water. EPA's use of the percent cropped area factors and the Index Reservoir scenario was reviewed by the FIFRA SAP in 1999 and 1998, respectively (Refs. 25 and 26).

In modeling potential surface water concentrations, EPA attempts to model areas of the country that are highly vulnerable to surface water contamination rather than simply model "typical" concentrations occurring across the nation. Consequently, EPA models exposures occurring in small highly agricultural watersheds in different growing areas throughout the country, over a 30 year period. The scenarios are designed to capture residue levels in drinking water from reservoirs with small watersheds with a large percentage of land use in agricultural production. EPA believes these assessments are likely reflective of a small subset of the watersheds across the country that maintain drinking water reservoirs, representing a drinking water source generally considered to be more vulnerable to frequent high concentrations of pesticides than most locations that could be used for crop production.

EPA uses the output of daily concentration values from tier two modeling as an input to DEEM-FCID, which combines water concentrations with drinking water consumption information in the daily diet to generate a distribution of exposures from consumption of drinking water contaminated with pesticides. These results are then used to calculate a probabilistic assessment of the aggregate human exposure and risk from residues in food and drinking water.

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FMC has criticized EPA's assessment for failing to account more fully for the percent of the crop treated (PCT) in its modeling. Uncertainty associated with PCT assumptions can be a major factor in EPA's drinking water exposure assessment for surface-water sources. Estimates of the percent of major crops (for example, corn) that are treated with pesticides are available at the state level, but are generally not available on a smaller scale suitable for estimating drinking water exposure in a watershed. In addition, the PCT should be assessed at a watershed-scale, aggregating all crops treated with the pesticide in a watershed. If state-scale estimates are used to account for PCT it will underestimate the risk for some of the drinking water facilities in the state as the state-wide estimate represents an average: values for individual facilities will be both lower and higher than the state-wide estimate. In some cases, the underestimate can be substantial if the application pattern tends to form cluster or pockets of high usage. Insecticides like carbofuran are particularly prone to this use pattern, as insect outbreaks often tend to be locally intense, rather than widespread. In addition, marginal use practice changes in a given watershed can substantially affect the percentage of the crop treated, and such changes are effectively impossible to track. Without data collected at a finer spatial scale, it is not possible to know whether pesticide usage is evenly dispersed through the state or is locally clustered. This results in large uncertainty in the drinking water exposure assessments when percent crop treated is moderate or low. Consequently, EPA does not typically include

such information in its surface-water exposure assessments.

However, in response to FMC's concerns, EPA performed a sensitivity analysis of an exposure assessment using a PCT in the watershed to determine the extent to which some consideration of this factor could meaningfully affect the outcome of the risk assessment. The registrant has at different times, suggested the application of a 5 or 10% crop treated based on county sales data. While substantial questions remain as to the support for these percentages for a given basin where carbofuran may be used, EPA used the upper figure for the purpose of conducting a sensitivity analysis. The results suggest that, even at levels below 10% crop treated, exposures from drinking water derived from surface waters can contribute significantly to the aggregate dietary risks, particularly for infants and children. For example, applying a 10% crop treated figure to the Nebraska corn scenario described above, in addition to the corn-PCA of 0.46 incorporated into that scenario, results in estimated exposures from water alone, ranging from 110% of the aPAD for children 6-12 to 390% of the aPAD for infants, assuming water treatment processes do not affect concentrations in drinking water consumed. Details on the assessments EPA conducted for other crop scenarios, which showed higher contributions from drinking water, can be found in Refs. 12, 13 and 47. Accordingly, these assessments suggest that EPA's use of PCA alone, rather than in conjunction with PCT, will not meaningfully affect the carbofuran risk assessment, as aggregate exposures would still exceed 100% of the aPAD.

In conclusion, the large difference between concentrations seen in the monitoring data on the low side, and the simulation modeling on the high side, is an indication of the uncertainty in the assessment for surface-water source drinking water exposure. The majority of drinking water concentrations resulting from use of carbofuran are likely to be occurring at higher concentrations than those measured in most monitoring studies, but below those estimated with simulation modeling; however the exact values are highly uncertain. However, the monitoring data show a consistent pattern of low concentrations, with the occasional, infrequent spike of high concentrations. Those infrequent high concentrations are consistent with EPA's modeling, which is intended to capture the exposure peaks. For a chemical with an acute risk, like carbofuran, the spikes or peaks in exposures, even though infrequent, are the most relevant for assessing the risks. And, as previously noted, the available monitoring has its own limitations for estimating exposure for risk assessment.

Further, the results of the modeling analyses provide critical insights regarding locations in the country where the potential for carbofuran contamination to surface water and associated drinking water sources are more likely. These locations include areas with soils prone to runoff (such as those high in clay or containing restrictive layers), in regions with intensive agriculture with crops on which carbofuran is used (*e.g.* corn), which have high rainfall amounts and/or are subject to intense storm events in the spring around the times applications are being made. Drinking water facilities with small basins tend to be more vulnerable, as it is more likely that a large

proportion of the crop acreage will be treated in small basins.

Apparently FMC also has determined that some drinking water facilities associated with surface source waters are vulnerable to carbofuran exposure. In the now withdrawn labels FMC proposed to require buffer zones around surface waters in certain locations of the country, presumably to protect surface water. The proposed buffers were for fields where soils were considered to be highly erodible. Buffers were to be 66 feet wide and were to be vegetated with "crop, seeded with grass, or other suitable crop". In 2000, EPA participated in the development of a guidance document on how to reduce pesticide runoff using conservation buffers (Ref. 55). Results of this effort found that properly designed buffers can reduce runoff of weakly absorbed pesticides like carbofuran by increasing filtration so that the pesticide can be trapped and degraded in the buffer. However, it is of critical importance that sheet flow be maintained across the buffer in order for this to occur. To ensure sheet flow, buffers need to be specifically designed for that purpose and they must be well-maintained, as over time sediment trapped in the buffer causes flow to become more channelized and the buffer then becomes ineffective. The guidance concludes that unmaintained, un-vegetated buffers around water bodies, often referred to a 'setback,' are ineffective in reducing pesticide movement to surface water.

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UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 09-1284 September Term 2010
EPA-74FR59608
Filed On: December 14, 2009

National Corn Growers Association, et al.,
Petitioners

v.

Environmental Protection Agency and Lisa Perez Jackson, Administrator,
Respondents

BEFORE: Ginsburg, Brown, and Griffith, Circuit Judges

ORDER

Upon consideration of the emergency motion for expedited review and stay pending review, which includes a request, in the alternative, for a remand, the opposition thereto, and the reply; and the motions for leave to file amicus curiae briefs responding to the emergency motion, it is

**ORDERED** that the motion for stay be denied. Petitioners have not satisfied the stringent standards required for a stay pending court review. See Washington Metropolitan Area Transit Commission v. Holiday Tours, Inc., 559 F.2d 841, 843 (D.C. Cir. 1977); D.C. Circuit Handbook of Practice and Internal Procedures 32-33 (2009). It is

**FURTHER ORDERED** that the request for a remand be denied. It is

**FURTHER ORDERED** that the motions for leave to file amicus curiae briefs be denied. This order is without prejudice to CropLife America, Defenders of Wildlife, American Bird Conservancy, Beyond Pesticides, Farmworker Justice, and Pesticide Action Network North America filing timely motions for leave to file amicus curiae briefs on the merits of the petition in review. See D.C. Cir. Rule 29(b). It is

**FURTHER ORDERED** that the following briefing schedule and format apply:

| | |
|---|---|
| Brief of Petitioners<br>(not to exceed 14,000 words) | January 4, 2010 |
| Appendix | January 4, 2010 |
| Brief of Respondents<br>(not to exceed 14,000 words) | February 3, 2010 |
| Reply Brief of Petitioners<br>(not to exceed 7,000) | February 10, 2010 |

The Clerk is directed to schedule the case for oral argument on the first available date following completion of briefing. Parties will be notified by separate order of the date of oral argument and composition of the merits panel. The court reminds the parties that:

> In cases involving direct review in this court of administrative actions, the brief of the appellant or petitioner must set forth the basis for the claim of standing. . . . When the appellant's or petitioner's standing is not apparent from the administrative record, the brief must include arguments and evidence establishing the claim of standing.

See D.C. Cir. Rule 28(a)(7).

Parties are strongly encouraged to hand deliver the paper copies of their briefs to the Clerk's office on the date due. Filing by mail may delay the processing of the brief. Additionally, counsel are reminded that if filing by mail, they must use a class of mail that is at least as expeditious as first-class mail. See Fed. R. App. P. 25(a). All briefs and appendices must contain the date that the case is scheduled for oral argument at the top of the cover. See D.C. Cir. Rule 28(a)(8).

Per Curiam

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

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No. 09-1284 September Term 2010
EPA-74FR59608
Filed On: October 19, 2010

National Corn Growers Association, et al.,
Petitioners

v.

Environmental Protection Agency and Lisa Perez Jackson, Administrator,
Respondents

BEFORE: Ginsburg, Tatel, and Griffith, Circuit Judges

ORDER

Upon consideration of petitioners' petition for panel rehearing filed on September 7, 2010, it is

ORDERED that the petition be denied.

Per Curiam

FOR THE COURT:
Mark J. Langer, Clerk
BY: /s/
Michael C. McGrail
Deputy Clerk

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 09-1284 September Term 2010
EPA-74FR59608
Filed On: October 19, 2010

National Corn Growers Association, et al.,
Petitioners

v.

Environmental Protection Agency and Lisa Perez Jackson, Administrator,
Respondents

BEFORE: Sentelle, Chief Judge, and Ginsburg, Henderson, Rogers, Tatel, Garland, Brown, Griffith, and Kavanaugh, Circuit Judges

ORDER

Upon consideration of petitioners' petition for rehearing en banc, the response thereto, and the absence of a request by any member of the court for a vote, it is

ORDERED that the petition be denied.

Per Curiam

FOR THE COURT:
Mark J. Langer, Clerk

BY: /s/
Michael C. McGrail
Deputy Clerk

# 21 U.S.C. § 346a

Title 21. Food and Drugs
Chapter 9. Federal Food, Drug, and Cosmetic Act
Subchapter IV. Food

## § 346a. Tolerances and exemptions for pesticide chemical residues

(a) Requirement for tolerance or exemption

(1) General rule

Except as provided in paragraph (2) or (3), any pesticide chemical residue in or on a food shall be deemed unsafe for the purpose of section 342(a)(2)(B) of this title unless—

(A) a tolerance for such pesticide chemical residue in or on such food is in effect under this section and the quantity of the residue is within the limits of the tolerance; or

(B) an exemption from the requirement of a tolerance is in effect under this section for the pesticide chemical residue.

For the purposes of this section, the term "food", when used as a noun without modification, shall mean a raw agricultural commodity or processed food.

(2) Processed food

Notwithstanding paragraph (1)—

(A) if a tolerance is in effect under this section for a pesticide chemical residue in or on a raw agricultural commodity, a pesticide chemical residue that is present in or on a processed food because the food is made from that raw

agricultural commodity shall not be considered unsafe within the meaning of section 342(a)(2)(B) of this title despite the lack of a tolerance for the pesticide chemical residue in or on the processed food if the pesticide chemical has been used in or on the raw agricultural commodity in conformity with a tolerance under this section, such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice, and the concentration of the pesticide chemical residue in the processed food is not greater than the tolerance prescribed for the pesticide chemical residue in the raw agricultural commodity; or

(B) if an exemption for the requirement for a tolerance is in effect under this section for a pesticide chemical residue in or on a raw agricultural commodity, a pesticide chemical residue that is present in or on a processed food because the food is made from that raw agricultural commodity shall not be considered unsafe within the meaning of section 342(a)(2)(B) of this title.

**(3) Residues of degradation products**

If a pesticide chemical residue is present in or on a food because it is a metabolite or other degradation product of a precursor substance that itself is a pesticide chemical or pesticide chemical residue, such a residue shall not be considered to be unsafe within the meaning of section 342(a)(2)(B) of this title despite the lack of a tolerance or exemption from the need for a tolerance for such residue in or on such food if—

(A) the Administrator has not determined that the degradation product is likely to pose any potential health risk from dietary exposure that is of a different type than, or of a greater significance than, any risk posed by dietary exposure to the precursor substance;

(B) either—

(i) a tolerance is in effect under this section for residues of the precursor substance in or on the food, and the combined level of residues of the degradation product and the precursor substance in or on the food is at or below the stoichiometrically equivalent level that would be permitted by the tolerance if the residue consisted only of the precursor substance rather than the degradation product; or

(ii) an exemption from the need for a tolerance is in effect under this section for residues of the precursor sub-stance in or on the food; and

(C) the tolerance or exemption for residues of the precursor substance does not state that it applies only to particular named substances and does not state that it does not apply to residues of the degradation product.

**(4) Effect of tolerance or exemption**

While a tolerance or exemption from the requirement for a tolerance is in effect under this section for a pesticide chemical residue with respect to any food, the food shall not by reason of bearing or containing any amount of such a residue be considered to be adulterated within the meaning of section 342(a)(1) of this title.

(b) Authority and standard for tolerance

(1) Authority

The Administrator may issue regulations establishing, modifying, or revoking a tolerance for a pesticide chemical residue in or on a food—

(A) in response to a petition filed under subsection (d) of this section; or

(B) on the Administrator's own initiative under subsection (e) of this section.

As used in this section, the term "modify" shall not mean expanding the tolerance to cover additional foods.

(2) Standard

(A) General rule

(i) Standard

The Administrator may establish or leave in effect a tolerance for a pesticide chemical residue in or on a food only if the Administrator determines that the tolerance is safe. The Administrator shall modify or revoke a tolerance if the Administrator determines it is not safe.

(ii) Determination of safety

As used in this section, the term "safe", with respect to a tolerance for a pesticide chemical residue, means that the Administrator has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.

(iii) **Rule of construction**

With respect to a tolerance, a pesticide chemical residue meeting the standard under clause (i) is not an eligible pesticide chemical residue for purposes of subparagraph (B).

(B) **Tolerances for eligible pesticide chemical residues**

(i) **Definition**

As used in this subparagraph, the term "eligible pesticide chemical residue" means a pesticide chemical residue as to which—

(I) the Administrator is not able to identify a level of exposure to the residue at which the residue will not cause or contribute to a known or anticipated harm to human health (referred to in this section as a "nonthreshold effect");

(II) the lifetime risk of experiencing the nonthreshold effect is appropriately assessed by quantitative risk assessment; and

(III) with regard to any known or anticipated harm to human health for which the Administrator is able to identify a level at which the residue will not cause such harm (referred to in this section as a "threshold effect"), the Administrator determines that the level of aggregate exposure is safe.

(ii) **Determination of tolerance**

Notwithstanding subparagraph (A)(i), a tolerance for an eligible pesticide chemical

residue may be left in effect or modified under this subparagraph if—

(I) at least one of the conditions described in clause (iii) is met; and

(II) both of the conditions described in clause (iv) are met.

**(iii) Conditions regarding use**

For purposes of clause (ii), the conditions described in this clause with respect to a tolerance for an eligible pesticide chemical residue are the following:

(I) Use of the pesticide chemical that produces the residue protects consumers from adverse effects on health that would pose a greater risk than the dietary risk from the residue.

(II) Use of the pesticide chemical that produces the residue is necessary to avoid a significant disruption in domestic production of an adequate, wholesome, and economical food supply.

**(iv) Conditions regarding risk**

For purposes of clause (ii), the conditions described in this clause with respect to a tolerance for an eligible pesticide chemical residue are the following:

(I) The yearly risk associated with the nonthreshold effect from aggregate exposure to the residue does not exceed 10 times the yearly risk that would be allowed under subparagraph (A) for such effect.

(II) The tolerance is limited so as to ensure that the risk over a lifetime associated with the nonthreshold effect from aggregate exposure to the residue is not greater than twice the lifetime risk that would be allowed under subparagraph (A) for such effect.

**(v) Review**

Five years after the date on which the Administrator makes a determination to leave in effect or modify a tolerance under this subparagraph, and thereafter as the Administrator deems appropriate, the Administrator shall determine, after notice and opportunity for comment, whether it has been demonstrated to the Administrator that a condition described in clause (iii)(I) or clause (iii)(II) continues to exist with respect to the tolerance and that the yearly and lifetime risks from aggregate exposure to such residue continue to comply with the limits specified in clause (iv). If the Administrator determines by such date that such demonstration has not been made, the Administrator shall, not later than 180 days after the date of such determination, issue a regulation under subsection (e)(1) of this section to modify or revoke the tolerance.

**(vi) Infants and children**

Any tolerance under this subparagraph shall meet the requirements of subparagraph (C).

(C) Exposure of infants and children

In establishing, modifying, leaving in effect, or revoking a tolerance or exemption for a pesticide chemical residue, the Administrator—

(i) shall assess the risk of the pesticide chemical residue based on—

(I) available information about consumption patterns among infants and children that are likely to result in disproportionately high consumption of foods containing or bearing such residue among infants and children in comparison to the general population;

(II) available information concerning the special susceptibility of infants and children to the pesticide chemical residues, including neurological differences between infants and children and adults, and effects of in utero exposure to pesticide chemicals; and

(III) available information concerning the cumulative effects on infants and children of such residues and other substances that have a common mechanism of toxicity; and

(ii) shall—

(I) ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue; and

(II) publish a specific determination regarding the safety of the pesticide chemical residue for infants and children.

The Secretary of Health and Human Services and the Secretary of Agriculture, in consultation with the Administrator, shall conduct surveys to document dietary exposure to pesticides among infants and children. In the case of threshold effects, for purposes of clause (ii)(I) an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre- and post-natal toxicity and completeness of the data with respect to expo-sure and toxicity to infants and children. Notwithstanding such requirement for an additional margin of safety, the Administrator may use a different margin of safety for the pesticide chemical residue only if, on the basis of reliable data, such margin will be safe for infants and children.

**(D) Factors**

In establishing, modifying, leaving in effect, or revoking a tolerance or exemption for a pesticide chemical residue, the Administrator shall consider, among other relevant factors—

(i) the validity, completeness, and reliability of the available data from studies of the pesticide chemical and pesticide chemical residue;

(ii) the nature of any toxic effect shown to be caused by the pesticide chemical or pesticide chemical residue in such studies;

(iii) available information concerning the relationship of the results of such studies to human risk;

(iv) available information concerning the dietary consumption patterns of consumers (and major identifiable subgroups of consumers);

(v) available information concerning the cumulative effects of such residues and other substances that have a common mechanism of toxicity;

(vi) available information concerning the aggregate exposure levels of consumers (and major identifiable subgroups of consumers) to the pesticide chemical residue and to other related substances, including dietary exposure under the tolerance and all other tolerances in effect for the pesticide chemical residue, and exposure from other non-occupational sources;

(vii) available information concerning the variability of the sensitivities of major identifiable subgroups of consumers;

(viii) such information as the Administrator may require on whether the pesticide chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects; and

(ix) safety factors which in the opinion of experts qualified by scientific training and experience to evaluate the safety of food additives are generally recognized as

appropriate for the use of animal experimentation data.

**(E) Data and information regarding anticipated and actual residue levels**

**(i) Authority**

In establishing, modifying, leaving in effect, or revoking a tolerance for a pesticide chemical residue, the Administrator may consider available data and information on the anticipated residue levels of the pesticide chemical in or on food and the actual residue levels of the pesticide chemical that have been measured in food, including residue data collected by the Food and Drug Administration.

**(ii) Requirement**

If the Administrator relies on anticipated or actual residue levels in establishing, modifying, or leaving in effect a tolerance, the Administrator shall pursuant to subsection (f)(1) of this section require that data be provided five years after the date on which the tolerance is established, modified, or left in effect, and thereafter as the Administrator deems appropriate, demonstrating that such residue levels are not above the levels so relied on. If such data are not so provided, or if the data do not demonstrate that the residue levels are not above the levels so relied on, the Administrator shall, not later than 180 days after the date on which the data were required to be provided, issue a regulation under subsection (e)(1) of this section, or an

order under subsection (f)(2) of this section, as appropriate, to modify or revoke the tolerance.

**(F) Percent of food actually treated**

In establishing, modifying, leaving in effect, or revoking a tolerance for a pesticide chemical residue, the Administrator may, when assessing chronic dietary risk, consider available data and information on the percent of food actually treated with the pesticide chemical (including aggregate pesticide use data collected by the Department of Agriculture) only if the Administrator—

(i) finds that the data are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide chemical residue;

(ii) finds that the exposure estimate does not understate exposure for any significant subpopulation group;

(iii) finds that, if data are available on pesticide use and consumption of food in a particular area, the population in such area is not dietarily exposed to residues above those estimated by the Administrator; and

(iv) provides for the periodic reevaluation of the estimate of anticipated dietary exposure.

**(3) Detection methods**

**(A) General rule**

A tolerance for a pesticide chemical residue in or on a food shall not be established or modified

by the Administrator unless the Administrator determines, after consultation with the Secretary, that there is a practical method for detecting and measuring the levels of the pesticide chemical residue in or on the food.

**(B) Detection limit**

A tolerance for a pesticide chemical residue in or on a food shall not be established at or modified to a level lower than the limit of detection of the method for detecting and measuring the pesticide chemical residue specified by the Administrator under subparagraph (A).

**(4) International standards**

In establishing a tolerance for a pesticide chemical residue in or on a food, the Administrator shall determine whether a maximum residue level for the pesticide chemical has been established by the Codex Alimentarius Commission. If a Codex maximum residue level has been established for the pesticide chemical and the Administrator does not propose to adopt the Codex level, the Administrator shall publish for public comment a notice explaining the reasons for departing from the Codex level.

**(c) Authority and standard for exemptions**

**(1) Authority**

The Administrator may issue a regulation establishing, modifying, or revoking an exemption from the requirement for a tolerance for a pesticide chemical residue in or on food—

(A) in response to a petition filed under subsection (d) of this section; or

(B) on the Administrator's initiative under subsection (e) of this section.

**(2) Standard**

**(A) General rule**

**(i) Standard**

The Administrator may establish or leave in effect an exemption from the requirement for a tolerance for a pesticide chemical residue in or on food only if the Administrator determines that the exemption is safe. The Administrator shall modify or revoke an exemption if the Administrator determines it is not safe.

**(ii) Determination of safety**

The term "safe", with respect to an exemption for a pesticide chemical residue, means that the Administrator has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.

**(B) Factors**

In making a determination under this paragraph, the Administrator shall take into account, among other relevant considerations, the considerations set forth in subparagraphs (C) and (D) of subsection (b)(2) of this section.

(3) Limitation

An exemption from the requirement for a tolerance for a pesticide chemical residue in or on food shall not be established or modified by the Administrator unless the Administrator determines, after consultation with the Secretary—

(A) that there is a practical method for detecting and measuring the levels of such pesticide chemical residue in or on food; or

(B) that there is no need for such a method, and states the reasons for such determination in issuing the regulation establishing or modifying the exemption.

(d) Petition for tolerance or exemption

(1) Petitions and petitioners

Any person may file with the Administrator a petition proposing the issuance of a regulation—

(A) establishing, modifying, or revoking a tolerance for a pesticide chemical residue in or on a food; or

(B) establishing, modifying, or revoking an exemption from the requirement of a tolerance for such a residue.

(2) Petition contents

(A) Establishment

A petition under paragraph (1) to establish a tolerance or exemption for a pesticide chemical residue shall be supported by such data and information as are specified in regulations issued by the Administrator, including—

(i)(I) an informative summary of the petition and of the data, information, and arguments submitted or cited in support of the petition; and

(II) a statement that the petitioner agrees that such summary or any information it contains may be published as a part of the notice of filing of the petition to be published under this subsection and as part of a proposed or final regulation issued under this section;

(ii) the name, chemical identity, and composition of the pesticide chemical residue and of the pesticide chemical that produces the residue;

(iii) data showing the recommended amount, frequency, method, and time of application of that pesticide chemical;

(iv) full reports of tests and investigations made with respect to the safety of the pesticide chemical, including full information as to the methods and controls used in conducting those tests and investigations;

(v) full reports of tests and investigations made with respect to the nature and amount of the pesticide chemical residue that is likely to remain in or on the food, including a description of the analytical methods used;

(vi) a practical method for detecting and measuring the levels of the pesticide chemical residue in or on the food, or for exemptions, a statement why such a method is not needed;

(vii) a proposed tolerance for the pesticide chemical residue, if a tolerance is proposed;

(viii) if the petition relates to a tolerance for a processed food, reports of investigations conducted using the processing method(s) used to produce that food;

(ix) such information as the Administrator may require to make the determination under subsection (b)(2)(C) of this section;

(x) such information as the Administrator may require on whether the pesticide chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects;

(xi) information regarding exposure to the pesticide chemical residue due to any tolerance or exemption already granted for such residue;

(xii) practical methods for removing any amount of the residue that would exceed any proposed tolerance; and

(xiii) such other data and information as the Administrator requires by regulation to support the petition.

If information or data required by this subparagraph is available to the Administrator, the person submitting the petition may cite the availability of the information or data in lieu of submitting it. The Administrator may require a petition to be accompanied by samples of the pesticide chemical with respect to which the petition is filed.

**(B) Modification or revocation**

The Administrator may by regulation establish the requirements for information and data to support a petition to modify or revoke a tolerance or to modify or revoke an exemption from the requirement for a tolerance.

**(3) Notice**

A notice of the filing of a petition that the Administrator determines has met the requirements of paragraph (2) shall be published by the Administrator within 30 days after such determination. The notice shall announce the availability of a description of the analytical methods available to the Administrator for the detection and measurement of the pesticide chemical residue with respect to which the petition is filed or shall set forth the petitioner's statement of why such a method is not needed. The notice shall include the summary required by paragraph (2)(A)(i)(I).

**(4) Actions by the Administrator**

**(A) In general**

The Administrator shall, after giving due consideration to a petition filed under paragraph (1) and any other information available to the Administrator—

(i) issue a final regulation (which may vary from that sought by the petition) establishing, modifying, or revoking a tolerance for the pesticide chemical residue or an exemption of the pesticide chemical residue from the requirement of a tolerance (which final regulation shall be issued

without further notice and without further period for public comment);

(ii) issue a proposed regulation under subsection (e) of this section, and thereafter issue a final regulation under such subsection; or

(iii) issue an order denying the petition.

**(B) Priorities**

The Administrator shall give priority to petitions for the establishment or modification of a tolerance or exemption for a pesticide chemical residue that appears to pose a significantly lower risk to human health from dietary exposure than pesticide chemical residues that have tolerances in effect for the same or similar uses.

**(C) Expedited review of certain petitions**

**(i) Date certain for review**

If a person files a complete petition with the Administrator proposing the issuance of a regulation establishing a tolerance or exemption for a pesticide chemical residue that presents a lower risk to human health than a pesticide chemical residue for which a tolerance has been left in effect or modified under subsection (b)(2)(B) of this section, the Administrator shall complete action on such petition under this paragraph within 1 year.

**(ii) Required determinations**

If the Administrator issues a final regulation establishing a tolerance or exemption for a safer pesticide chemical residue under clause (i), the Administrator

shall, not later than 180 days after the date on which the regulation is issued, determine whether a condition described in subclause (I) or (II) of subsection (b)(2)(B)(iii) of this section continues to exist with respect to a tolerance that has been left in effect or modified under subsection (b)(2)(B) of this section. If such condition does not continue to exist, the Administrator shall, not later than 180 days after the date on which the determination under the preceding sentence is made, issue a regulation under subsection (e)(1) of this section to modify or revoke the tolerance.

(e) **Action on Administrator's own initiative**

**(1) General rule**

The Administrator may issue a regulation—

(A) establishing, modifying, suspending under subsection (*l*)(3) of this section, or revoking a tolerance for a pesticide chemical or a pesticide chemical residue;

(B) establishing, modifying, suspending under subsection (*l*)(3) of this section, or revoking an exemption of a pesticide chemical residue from the requirement of a tolerance; or

(C) establishing general procedures and requirements to implement this section.

**(2) Notice**

Before issuing a final regulation under paragraph (1), the Administrator shall issue a notice of proposed rulemaking and provide a period of not less than 60 days for public comment on the

proposed regulation, except that a shorter period for comment may be provided if the Administrator for good cause finds that it would be in the public interest to do so and states the reasons for the finding in the notice of proposed rulemaking.

(f) **Special data requirements**

**(1) Requiring submission of additional data**

If the Administrator determines that additional data or information are reasonably required to support the continuation of a tolerance or exemption that is in effect under this section for a pesticide chemical residue on a food, the Administrator shall—

(A) issue a notice requiring the person holding the pesticide registrations associated with such tolerance or exemption to submit the data or information under section 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136a(c)(2)(B)];

(B) issue a rule requiring that testing be conducted on a substance or mixture under section 4 of the Toxic Substances Control Act - 15 U.S.C. 2603]; or

(C) publish in the Federal Register, after first providing notice and an opportunity for comment of not less than 60 days' duration, an order—

(i) requiring the submission to the Administrator by one or more interested persons of a notice identifying the person or persons who will submit the required data and information;

(ii) describing the type of data and information required to be submitted to the Administrator and stating why the data and information could not be obtained under the authority of section 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136a(c)(2)(B)] or section 4 of the Toxic Substances Control Act [15 U.S.C. 2603];

(iii) describing the reports of the Administrator required to be prepared during and after the collection of the data and information;

(iv) requiring the submission to the Administrator of the data, information, and reports referred to in clauses (ii) and (iii); and

(v) establishing dates by which the submissions described in clauses (i) and (iv) must be made.

The Administrator may under subparagraph (C) revise any such order to correct an error. The Administrator may under this paragraph require data or information pertaining to whether the pesticide chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects.

**(2) Noncompliance**

If a submission required by a notice issued in accordance with paragraph (1)(A), a rule issued under paragraph (1)(B), or an order issued under paragraph (1)(C) is not made by the time specified in such notice, rule, or order, the Administrator may by order published in the Federal Register modify or revoke the tolerance or exemption in

question. In any review of such an order under subsection (g)(2) of this section, the only material issue shall be whether a submission required under paragraph (1) was not made by the time specified.

**(g) Effective date, objections, hearings, and administrative review**

**(1) Effective date**

A regulation or order issued under subsection (d)(4), (e)(1), or (f)(2) of this section shall take effect upon publication unless the regulation or order specifies otherwise. The Administrator may stay the effectiveness of the regulation or order if, after issuance of such regulation or order, objections are filed with respect to such regulation or order pursuant to paragraph (2).

**(2) Further proceedings**

**(A) Objections**

Within 60 days after a regulation or order is issued under subsection (d)(4), (e)(1)(A), (e)(1)(B), (f)(2), (n)(3), or (n)(5)(C) of this section, any person may file objections thereto with the Administrator, specifying with particularity the provisions of the regulation or order deemed objectionable and stating reasonable grounds therefor. If the regulation or order was issued in response to a petition under subsection (d)(1) of this section, a copy of each objection filed by a person other than the petitioner shall be served by the Administrator on the petitioner.

(B) Hearing

An objection may include a request for a public evidentiary hearing upon the objection. The Administrator shall, upon the initiative of the Administrator or upon the request of an interested person and after due notice, hold a public evidentiary hearing if and to the extent the Administrator determines that such a public hearing is necessary to receive factual evidence relevant to material issues of fact raised by the objections. The presiding officer in such a hearing may authorize a party to obtain discovery from other persons and may upon a showing of good cause made by a party issue a subpoena to compel testimony or production of documents from any person. The presiding officer shall be governed by the Federal Rules of Civil Procedure in making any order for the protection of the witness or the content of documents produced and shall order the payment of reasonable fees and expenses as a condition to requiring testimony of the witness. On contest, such a subpoena may be enforced by a Federal district court.

(C) Final decision

As soon as practicable after receiving the arguments of the parties, the Administrator shall issue an order stating the action taken upon each such objection and setting forth any revision to the regulation or prior order that the Administrator has found to be warranted. If a hearing was held under

subparagraph (B), such order and any revision to the regulation or prior order shall, with respect to questions of fact at issue in the hearing, be based only on substantial evidence of record at such hearing, and shall set forth in detail the findings of facts and the conclusions of law or policy upon which the order or regulation is based.

(h) **Judicial review**

**(1) Petition**

In a case of actual controversy as to the validity of any regulation issued under subsection (e)(1)(C) of this section, or any order issued under subsection (f)(1)(C) or (g)(2)(C) of this section, or any regulation that is the subject of such an order, any person who will be adversely affected by such order or regulation may obtain judicial review by filing in the United States Court of Appeals for the circuit wherein that person resides or has its principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within 60 days after publication of such order or regulation, a petition praying that the order or regulation be set aside in whole or in part.

**(2) Record and jurisdiction**

A copy of the petition under paragraph (1) shall be forthwith transmitted by the clerk of the court to the Administrator, or any officer designated by the Administrator for that purpose, and thereupon the Administrator shall file in the court the record of the proceedings on which the Administrator based the order or regulation, as provided in section 2112 of title 28. Upon the filing of such a petition, the

court shall have exclusive jurisdiction to affirm or set aside the order or regulation complained of in whole or in part. As to orders issued following a public evidentiary hearing, the findings of the Administrator with respect to questions of fact shall be sustained only if supported by substantial evidence when considered on the record as a whole.

**(3) Additional evidence**

If a party applies to the court for leave to adduce additional evidence and shows to the satisfaction of the court that the additional evidence is material and that there were reasonable grounds for the failure to adduce the evidence in the proceeding before the Administrator, the court may order that the additional evidence (and evidence in rebuttal thereof) shall be taken before the Administrator in the manner and upon the terms and conditions the court deems proper. The Administrator may modify prior findings as to the facts by reason of the additional evidence so taken and may modify the order or regulation accordingly. The Administrator shall file with the court any such modified finding, order, or regulation.

**(4) Final judgment; Supreme Court review**

The judgment of the court affirming or setting aside, in whole or in part, any regulation or any order and any regulation which is the subject of such an order shall be final, subject to review by the Supreme Court of the United States as provided in section 1254 of title 28. The commencement of proceedings under this subsection shall not, unless specifically ordered by the court to the contrary, operate as a stay of a regulation or order.

**(5) Application**

Any issue as to which review is or was obtainable under this subsection shall not be the subject of judicial review under any other provision of law.

**(i) Confidentiality and use of data**

**(1) General rule**

Data and information that are or have been submitted to the Administrator under this section or section 348 of this title in support of a tolerance or an exemption from a tolerance shall be entitled to confidential treatment for reasons of business confidentiality and to exclusive use and data compensation to the same extent provided by sections 3 and 10 of the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136a, 136h].

**(2) Exceptions**

**(A) In general**

Data and information that are entitled to confidential treatment under paragraph (1) may be disclosed, under such security requirements as the Administrator may provide by regulation, to—

(i) employees of the United States authorized by the Administrator to examine such data and information in the carrying out of their official duties under this chapter or other Federal statutes intended to protect the public health; or

(ii) contractors with the United States authorized by the Administrator to examine such data and information in the carrying out

of contracts under this chapter or such statutes.

**(B) Congress**

This subsection does not authorize the withholding of data or information from either House of Congress or from, to the extent of matter within its jurisdiction, any committee or subcommittee of such committee or any joint committee of Congress or any subcommittee of such joint committee.

**(3) Summaries**

Notwithstanding any provision of this subsection or other law, the Administrator may publish the informative summary required by subsection (d)(2)(A)(i) of this section and may, in issuing a proposed or final regulation or order under this section, publish an informative summary of the data relating to the regulation or order.

**(j) Status of previously issued regulations**

**(1) Regulations under section 346**

Regulations affecting pesticide chemical residues in or on raw agricultural commodities promulgated, in accordance with section 371(e) of this title, under the authority of section 346(a) of this title upon the basis of public hearings instituted before January 1, 1953, shall be deemed to be regulations issued under this section and shall be subject to modification or revocation under subsections (d) and (e) of this section, and shall be subject to review under subsection (q) of this section.

**(2) Regulations under section 348**

Regulations that established tolerances for substances that are pesticide chemical residues in or on processed food, or that otherwise stated the conditions under which such pesticide chemicals could be safely used, and that were issued under section 348 of this title on or before August 3, 1996, shall be deemed to be regulations issued under this section and shall be subject to modification or revocation under subsection (d) or (e) of this section, and shall be subject to review under subsection (q) of this section.

**(3) Regulations under section 346a**

Regulations that established tolerances or exemptions under this section that were issued on or before August 3, 1996, shall remain in effect unless modified or revoked under subsection (d) or (e) of this section, and shall be subject to review under subsection (q) of this section.

**(4) Certain substances**

With respect to a substance that is not included in the definition of the term "pesticide chemical" under section 321(q)(1) of this title but was so included on the day before October 30, 1998, the following applies as of October 30, 1998:

(A) Notwithstanding paragraph (2), any regulation applying to the use of the substance that was in effect on the day before October 30, 1998, and was on such day deemed in such paragraph to have been issued under this section, shall be considered to have been issued under section 348 of this title.

(B) Notwithstanding paragraph (3), any regulation applying to the use of the substance that was in effect on such day and was issued under this section (including any such regulation issued before August 3, 1996) is deemed to have been issued under section 348 of this title.

**(k) Transitional provision**

If, on the day before August 3, 1996, a substance that is a pesticide chemical was, with respect to a particular pesticidal use of the substance and any resulting pesticide chemical residue in or on a particular food—

(1) regarded by the Administrator or the Secretary as generally recognized as safe for use within the meaning of the provisions of subsection (a) of this section or section 321(s) of this title as then in effect; or

(2) regarded by the Secretary as a substance described by section 321(s)(4) of this title;

such a pesticide chemical residue shall be regarded as exempt from the requirement for a tolerance, as of August 3, 1996. The Administrator shall by regulation indicate which substances are described by this subsection. Any exemption under this subsection may be modified or revoked as if it had been issued under subsection (c) of this section.

**(*l*) Harmonization with action under other laws**

**(1) Coordination with FIFRA**

To the extent practicable and consistent with the review deadlines in subsection (q) of this section, in issuing a final rule under this subsection that suspends or revokes a tolerance or exemption for a

pesticide chemical residue in or on food, the Administrator shall coordinate such action with any related necessary action under the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 et seq.].

(2) **Revocation of tolerance or exemption following cancellation of associated registrations**

If the Administrator, acting under the Federal Insecticide, Fungicide, and Rodenticide Act, cancels the registration of each pesticide that contains a particular pesticide chemical and that is labeled for use on a particular food, or requires that the registration of each such pesticide be modified to prohibit its use in connection with the production, storage, or transportation of such food, due in whole or in part to dietary risks to humans posed by residues of that pesticide chemical on that food, the Administrator shall revoke any tolerance or exemption that allows the presence of the pesticide chemical, or any pesticide chemical residue that results from its use, in or on that food. Subsection (e) of this section shall apply to actions taken under this paragraph. A revocation under this paragraph shall become effective not later than 180 days after—

(A) the date by which each such cancellation of a registration has become effective; or

(B) the date on which the use of the canceled pesticide becomes unlawful under the terms of the cancellation, whichever is later.

(3) **Suspension of tolerance or exemption following suspension of associated registrations**

**(A) Suspension**

If the Administrator, acting under the Federal Insecticide, Fungicide, and Rodenticide Act, suspends the use of each registered pesticide that contains a particular pesticide chemical and that is labeled for use on a particular food, due in whole or in part to dietary risks to humans posed by residues of that pesticide chemical on that food, the Administrator shall suspend any tolerance or exemption that allows the presence of the pesticide chemical, or any pesticide chemical residue that results from its use, in or on that food. Subsection (e) of this section shall apply to actions taken under this paragraph. A suspension under this paragraph shall become effective not later than 60 days after the date by which each such suspension of use has become effective.

**(B) Effect of suspension**

The suspension of a tolerance or exemption under subparagraph (A) shall be effective as long as the use of each associated registration of a pesticide is suspended under the Federal Insecticide, Fungicide, and Rodenticide Act. While a suspension of a tolerance or exemption is effective the tolerance or exemption shall not be considered to be in effect. If the suspension of use of the pesticide under that Act is terminated, leaving the registration of the pesticide for such use in effect under that Act,

the Administrator shall rescind any associated suspension of tolerance or exemption.

**(4) Tolerances for unavoidable residues**

In connection with action taken under paragraph (2) or (3), or with respect to pesticides whose registrations were suspended or canceled prior to August 3, 1996, under the Federal Insecticide, Fungicide, and Rodenticide Act, if the Administrator determines that a residue of the canceled or suspended pesticide chemical will unavoidably persist in the environment and thereby be present in or on a food, the Administrator may establish a tolerance for the pesticide chemical residue. In establishing such a tolerance, the Administrator shall take into account both the factors set forth in subsection (b)(2) of this section and the unavoidability of the residue. Subsection (e) of this section shall apply to the establishment of such tolerance. The Administrator shall review any such tolerance periodically and modify it as necessary so that it allows no greater level of the pesticide chemical residue than is unavoidable.

**(5) Pesticide residues resulting from lawful application of pesticide**

Notwithstanding any other provision of this chapter, if a tolerance or exemption for a pesticide chemical residue in or on a food has been revoked, suspended, or modified under this section, an article of that food shall not be deemed unsafe solely because of the presence of such pesticide chemical residue in or on such food if it is shown to the satisfaction of the Secretary that—

(A) the residue is present as the result of an application or use of a pesticide at a time and in a manner that was lawful under the Federal Insecticide, Fungicide, and Rodenticide Act; and

(B) the residue does not exceed a level that was authorized at the time of that application or use to be present on the food under a tolerance, exemption, food additive regulation, or other sanction then in effect under this chapter;

unless, in the case of any tolerance or exemption revoked, suspended, or modified under this subsection or subsection (d) or (e) of this section, the Administrator has issued a determination that consumption of the legally treated food during the period of its likely availability in commerce will pose an unreasonable dietary risk.

**(6) Tolerance for use of pesticides under an emergency exemption**

If the Administrator grants an exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136p) for a pesticide chemical, the Administrator shall establish a tolerance or exemption from the requirement for a tolerance for the pesticide chemical residue. Such a tolerance or exemption from a tolerance shall have an expiration date. The Administrator may establish such a tolerance or exemption without providing notice or a period for comment on the tolerance or exemption. The Administrator shall promulgate regulations within 365 days after August 3, 1996, governing the establishment of tolerances and exemptions under this paragraph. Such regulations shall be consistent with the safety standard under subsections (b)(2) and (c)(2) of this

section and with section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act.

(m) **Fees**

**(1) Amount**

The Administrator shall by regulation require the payment of such fees as will in the aggregate, in the judgment of the Administrator, be sufficient over a reasonable term to provide, equip, and maintain an adequate service for the performance of the Administrator's functions under this section. Under the regulations, the performance of the Administrator's services or other functions under this section, including—

(A) the acceptance for filing of a petition submitted under subsection (d) of this section;

(B) establishing, modifying, leaving in effect, or revoking a tolerance or establishing, modifying, leaving in effect, or revoking an exemption from the requirement for a tolerance under this section;

(C) the acceptance for filing of objections under subsection (g) of this section; or

(D) the certification and filing in court of a transcript of the proceedings and the record under subsection (h) of this section;

may be conditioned upon the payment of such fees. The regulations may further provide for waiver or refund of fees in whole or in part when in the judgment of the Administrator such a waiver or refund is equitable and not contrary to the purposes of this subsection.

(2) Deposit

All fees collected under paragraph (1) shall be deposited in the Reregistration and Expedited Processing Fund created by section 4(k) of the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136a-1(k)]. Such fees shall be available to the Administrator, without fiscal year limitation, for the performance of the Administrator's services or functions as specified in paragraph (1).

(3) Prohibition

During the period beginning on the effective date of the Pesticide Registration Improvement Renewal Act and ending on September 30, 2012, the Administrator shall not collect any tolerance fees under paragraph (1).

(n) National uniformity of tolerances

(1) "Qualifying pesticide chemical residue" defined

For purposes of this subsection, the term "qualifying pesticide chemical residue" means a pesticide chemical residue resulting from the use, in production, processing, or storage of a food, of a pesticide chemical that is an active ingredient and that—

(A) was first approved for such use in a registration of a pesticide issued under section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136a(c)(5)] on or after April 25, 1985, on the basis of data determined by the Administrator to meet all applicable requirements for data prescribed by regulations

in effect under that Act [7 U.S.C. 136 et seq.] on April 25, 1985; or

(B) was approved for such use in a reregistration eligibility determination issued under section 4(g) of that Act [7 U.S.C. 136a-1(g)] on or after August 3, 1996.

**(2) Qualifying Federal determination**

For purposes of this subsection, the term "qualifying Federal determination" means a tolerance or exemption from the requirement for a tolerance for a qualifying pesticide chemical residue that—

(A) is issued under this section after August 3, 1996, and determined by the Administrator to meet the standard under subsection (b)(2)(A) (in the case of a tolerance) or (c)(2) (in the case of an exemption) of this section; or

(B)(i) pursuant to subsection (j) of this section is remaining in effect or is deemed to have been issued under this section, or is regarded under subsection (k) of this section as exempt from the requirement for a tolerance; and

(ii) is determined by the Administrator to meet the standard under subsection (b)(2)(A) (in the case of a tolerance) or (c)(2) (in the case of an exemption) of this section.

**(3) Limitation**

The Administrator may make the determination described in paragraph (2)(B)(ii) only by issuing a rule in accordance with the procedure set forth in subsection (d) or (e) of this section and only if the Administrator issues a proposed rule and allows a period of not less than 30 days for comment on the

proposed rule. Any such rule shall be reviewable in accordance with subsections (g) and (h) of this section.

**(4) State authority**

Except as provided in paragraphs (5), (6), and (8) no State or political subdivision may establish or enforce any regulatory limit on a qualifying pesticide chemical residue in or on any food if a qualifying Federal determination applies to the presence of such pesticide chemical residue in or on such food, unless such State regulatory limit is identical to such qualifying Federal determination. A State or political subdivision shall be deemed to establish or enforce a regulatory limit on a pesticide chemical residue in or on a food if it purports to prohibit or penalize the production, processing, shipping, or other handling of a food because it contains a pesticide residue (in excess of a prescribed limit).

**(5) Petition procedure**

**(A) In general**

Any State may petition the Administrator for authorization to establish in such State a regulatory limit on a qualifying pesticide chemical residue in or on any food that is not identical to the qualifying Federal determination applicable to such qualifying pesticide chemical residue.

**(B) Petition requirements**

Any petition under subparagraph (A) shall—

(i) satisfy any requirements prescribed, by rule, by the Administrator; and

(ii) be supported by scientific data about the pesticide chemical residue that is the subject of the petition or about chemically related pesticide chemical residues, data on the consumption within such State of food bearing the pesticide chemical residue, and data on exposure of humans within such State to the pesticide chemical residue.

**(C) Authorization**

The Administrator may, by order, grant the authorization described in subparagraph (A) if the Administrator determines that the proposed State regulatory limit—

(i) is justified by compelling local conditions; and

(ii) would not cause any food to be a violation of Federal law.

**(D) Treatment**

In lieu of any action authorized under subparagraph (C), the Administrator may treat a petition under this paragraph as a petition under subsection (d) of this section to modify or revoke a tolerance or an exemption. If the Administrator determines to treat a petition under this paragraph as a petition under subsection (d) of this section, the Administrator shall thereafter act on the petition pursuant to subsection (d) of this section.

**(E) Review**

Any order of the Administrator granting or denying the authorization described in subparagraph (A) shall be subject to review in

the manner described in subsections (g) and (h) of this section.

**(6) Urgent petition procedure**

Any State petition to the Administrator pursuant to paragraph (5) that demonstrates that consumption of a food containing such pesticide residue level during the period of the food's likely availability in the State will pose a significant public health threat from acute exposure shall be considered an urgent petition. If an order by the Administrator to grant or deny the requested authorization in an urgent petition is not made within 30 days of receipt of the petition, the petitioning State may establish and enforce a temporary regulatory limit on a qualifying pesticide chemical residue in or on the food. The temporary regulatory limit shall be validated or terminated by the Administrator's final order on the petition.

**(7) Residues from lawful application**

No State or political subdivision may enforce any regulatory limit on the level of a pesticide chemical residue that may appear in or on any food if, at the time of the application of the pesticide that resulted in such residue, the sale of such food with such residue level was lawful under this section and under the law of such State, unless the State demonstrates that consumption of the food containing such pesticide residue level during the period of the food's likely availability in the State will pose an unreasonable dietary risk to the health of persons within such State.

**(8) Savings**

Nothing in this chapter preempts the authority of any State or political subdivision to require that a

food containing a pesticide chemical residue bear or be the subject of a warning or other statement relating to the presence of the pesticide chemical residue in or on such food.

**(o) Consumer right to know**

Not later than 2 years after August 3, 1996, and annually thereafter, the Administrator shall, in consultation with the Secretary of Agriculture and the Secretary of Health and Human Services, publish in a format understandable to a lay person, and distribute to large retail grocers for public display (in a manner determined by the grocer), the following information, at a minimum:

(1) A discussion of the risks and benefits of pesticide chemical residues in or on food purchased by consumers.

(2) A listing of actions taken under subparagraph (B) of subsection (b)(2) of this section that may result in pesticide chemical residues in or on food that present a yearly or lifetime risk above the risk allowed under subparagraph (A) of such subsection, and the food on which the pesticide chemicals producing the residues are used.

(3) Recommendations to consumers for reducing dietary exposure to pesticide chemical residues in a manner consistent with maintaining a healthy diet, including a list of food that may reasonably substitute for food listed under paragraph (2).

Nothing in this subsection shall prevent retail grocers from providing additional information.

(p) Estrogenic substances screening program

(1) Development

Not later than 2 years after August 3, 1996, the Administrator shall in consultation with the Secretary of Health and Human Services develop a screening program, using appropriate validated test systems and other scientifically relevant information, to determine whether certain substances may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect as the Administrator may designate.

(2) Implementation

Not later than 3 years after August 3, 1996, after obtaining public comment and review of the screening program described in paragraph (1) by the scientific advisory panel established under section 25(d) of the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136w(d)] or the science advisory board established by section 4365of Title 42, the Administrator shall implement the program.

(3) Substances

In carrying out the screening program described in paragraph (1), the Administrator—

(A) shall provide for the testing of all pesticide chemicals; and

(B) may provide for the testing of any other substance that may have an effect that is cumulative to an effect of a pesticide chemical if the Administrator determines that a substantial population may be exposed to such sub-stance.

**(4) Exemption**

Notwithstanding paragraph (3), the Administrator may, by order, exempt from the requirements of this section a biologic substance or other substance if the Administrator determines that the substance is anticipated not to produce any effect in humans similar to an effect produced by a naturally occurring estrogen.

**(5) Collection of information**

**(A) In general**

The Administrator shall issue an order to a registrant of a substance for which testing is required under this subsection, or to a person who manufactures or imports a substance for which testing is required under this subsection, to conduct testing in accordance with the screening program described in paragraph (1), and submit information obtained from the testing to the Administrator, within a reasonable time period that the Administrator determines is sufficient for the generation of the information.

**(B) Procedures**

To the extent practicable the Administrator shall minimize duplicative testing of the same substance for the same endocrine effect, develop, as appropriate, procedures for fair and equitable sharing of test costs, and develop, as necessary, procedures for handling of confidential business information.

**(C) Failure of registrants to submit information**

**(i) Suspension**

If a registrant of a substance referred to in paragraph (3)(A) fails to comply with an order under subparagraph (A) of this paragraph, the Administrator shall issue a notice of intent to suspend the sale or distribution of the substance by the registrant. Any suspension proposed under this paragraph shall become final at the end of the 30-day period beginning on the date that the registrant receives the notice of intent to suspend, unless during that period a person adversely affected by the notice requests a hearing or the Administrator determines that the registrant has complied fully with this paragraph.

**(ii) Hearing**

If a person requests a hearing under clause (i), the hearing shall be conducted in accordance with section 554 of title 5. The only matter for resolution at the hearing shall be whether the registrant has failed to comply with an order under subparagraph (A) of this paragraph. A decision by the Administrator after completion of a hearing shall be considered to be a final agency action.

**(iii) Termination of suspensions**

The Administrator shall terminate a suspension under this subparagraph issued with respect to a registrant if the Administrator determines that the registrant has complied fully with this paragraph.

(D) Noncompliance by other persons

Any person (other than a registrant) who fails to comply with an order under subparagraph (A) shall be liable for the same penalties and sanctions as are provided under section 16 of the Toxic Substances Control Act [15 U.S.C. 2615] in the case of a violation referred to in that section. Such penalties and sanctions shall be assessed and imposed in the same manner as provided in such section 16.

(6) Agency action

In the case of any substance that is found, as a result of testing and evaluation under this section, to have an endocrine effect on humans, the Administrator shall, as appropriate, take action under such statutory authority as is available to the Administrator, including consideration under other sections of this chapter, as is necessary to ensure the protection of public health.

(7) Report to Congress

Not later than 4 years after August 3, 1996, the Administrator shall prepare and submit to Congress a report containing—

(A) the findings of the Administrator resulting from the screening program described in paragraph (1);

(B) recommendations for further testing needed to evaluate the impact on human health of the substances tested under the screening program; and

(C) recommendations for any further actions (including any action described in paragraph (6))

that the Administrator determines are appropriate based on the findings.

**(q) Schedule for review**

**(1) In general**

The Administrator shall review tolerances and exemptions for pesticide chemical residues in effect on the day before August 3, 1996, as expeditiously as practicable, assuring that—

(A) 33 percent of such tolerances and exemptions are reviewed within 3 years of August 3, 1996;

(B) 66 percent of such tolerances and exemptions are reviewed within 6 years of August 3, 1996; and

(C) 100 percent of such tolerances and exemptions are reviewed within 10 years of August 3, 1996.

In conducting a review of a tolerance or exemption, the Administrator shall determine whether the tolerance or exemption meets the requirements of subsections (b)(2) or (c)(2) of this section and shall, by the deadline for the review of the tolerance or exemption, issue a regulation under subsection (d)(4) or (e)(1) of this section to modify or revoke the tolerance or exemption if the tolerance or exemption does not meet such requirements.

**(2) Priorities**

In determining priorities for reviewing tolerances and exemptions under paragraph (1), the Administrator shall give priority to the review of the tolerances or exemptions that appear to pose the greatest risk to public health.

**(3) Publication of schedule**

Not later than 12 months after August 3, 1996, the Administrator shall publish a schedule for review of tolerances and exemptions established prior to August 3, 1996. The determination of priorities for the review of tolerances and exemptions pursuant to this subsection is not a rulemaking and shall not be subject to judicial review, except that failure to take final action pursuant to the schedule established by this paragraph shall be subject to judicial review.

**(r) Temporary tolerance or exemption**

The Administrator may, upon the request of any person who has obtained an experimental permit for a pesticide chemical under the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 et seq.] or upon the Administrator's own initiative, establish a temporary tolerance or exemption for the pesticide chemical residue for the uses covered by the permit. Subsections (b)(2), (c)(2), (d), and (e) of this section shall apply to actions taken under this subsection.

**(s) Savings clause**

Nothing in this section shall be construed to amend or modify the provisions of the Toxic Substances Control Act [15 U.S.C. 2601 et seq.] or the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 et seq.].

# 40 C.F.R. § 178.20

Title 40. Protection of Environment
Chapter I. Environmental Protection Agency
Subchapter E. Pesticide Programs
Part 178. Objections and Requests for Hearings
Subpart B. Procedures for Filing Objections and Requests for Hearing

## § 178.20 Right to submit objections and requests for a hearing

(a) On or before the 60th day after the date of publication in the Federal Register of an order under part 180 of this chapter establishing, modifying, or revoking a regulation, or denying all or any portion of a petition, a person adversely affected by such order or petition denial may submit, in accordance with § 178.25, one or more written objections to the order (or to the action that is the subject of the order).

(b) A person may include with any such objection a written request for an evidentiary hearing on such objection in accordance with § 178.27.

(c) A person who submits objections need not request a hearing. For instance, if the person's objections are of a purely legal or policy nature, a hearing request would be inappropriate; the purpose of an evidentiary hearing is to resolve factual disputes. The Administrator will rule on the objections, whether or not a hearing is requested.

(d) As a matter of discretion, the Administrator may order a hearing on an objection even though no person has requested a hearing.

# 40 C.F.R. § 178.30

Code of Federal Regulations
Title 40. Protection of Environment
Chapter I. Environmental Protection Agency
Subchapter E. Pesticide Programs
Part 178. Objections and Requests for Hearings
Subpart B. Procedures for Filing Objections and Requests for Hearing

**§ 178.30 Response by Administrator to objections and to requests for hearing.**

The Administrator will respond to objections, and to requests for a hearing on such objections, as set forth in this section.

(a) *Denial of objections that are improperly submitted or that seek an unavailable form of relief.* The Administrator will by order issued under § 178.37 deny each objection and each request for a hearing that is included with such an objection, if:

(1) The objection is found not to conform to § 178.25.

(2) The action requested by the objection is inconsistent with any provision of FFDCA.

(3) The action requested by the objection is inconsistent with any generic, e.g., non-chemical specific, interpretation of a provision of FFDCA in any regulation in this chapter (the proper procedure in such a case is for the person to petition for an amendment of the regulation involved).

(b) *Denial of improperly submitted requests for hearing.* The Administrator will then determine

whether any objection that has not been denied under paragraph (a) of this section was accompanied by a request for an evidentiary hearing that conforms to § 178.27. The Administrator will deny under § 178.37 each request that does not conform to § 178.27.

(c) *Grouping of certain related objections.* If the Administrator then finds (1) That two or more undenied objections are substantially similar, or are related in such a way that any judicial review of the Administrator's action on those objections should occur at the same time, and (2) that one or more of those objections was accompanied by an undenied request for an evidentiary hearing on that objection, the Administrator will treat those objections as a group and will rule on them only after ruling under § 178.32 on the associated request for hearing.

(d) *Rulings on objections for which a request for hearing has been granted.* If the Administrator rules under § 178.32 that an evidentiary hearing should be held on an objection, the Administrator will resolve the issues raised by any other objection grouped with it under paragraph (c) of this section in conjunction with the evidentiary hearing upon which the hearing request was granted, unless the Administrator for good cause determines otherwise.

(e) *Rulings on objections for which no request for hearing was received, or for which each request for hearing was denied.* Except as provided in paragraphs (c) and (d) of this section, if no hearing was requested on an objection, or if each such request that was made is denied under the criteria of paragraphs (a) or (b) of this section or § 178.32(b), the Administrator will rule on the objection under § 178.37.

# 40 C.F.R. § 178.32

Code of Federal Regulations
Title 40. Protection of Environment
Chapter I. Environmental Protection Agency
Subchapter E. Pesticide Programs
Part 178. Objections and Requests for Hearings
Subpart B. Procedures for Filing Objections and Requests for Hearing

## § 178.32 Rulings on requests for hearing.

(a) In the case of each request for an evidentiary hearing that was not denied under § 178.30(a) or (b), the Administrator will determine whether such a hearing on one or more of the objections is justified, and will publish in the Federal Register the determination in an order issued under § 178.37 or a Notice of Hearing issued under § 179.20 of this chapter. If some requests for a hearing are denied and others pertaining to the same order or regulation are granted, the denial order and the hearing notice may be combined into a single document and shall be issued at the same time unless the Administrator for good cause determines otherwise.

(b) A request for an evidentiary hearing will be granted if the Administrator determines that the material submitted shows the following:

(1) There is a genuine and substantial issue of fact for resolution at a hearing. An evidentiary hearing will not be granted on issues of policy or law.

(2) There is a reasonable possibility that available evidence identified by the requestor would, if

established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary. An evidentiary hearing will not be granted on the basis of mere allegations, denials, or general descriptions of positions and contentions, nor if the Administrator concludes that the data and information submitted, even if accurate, would be insufficient to justify the factual determination urged.

(3) Resolution of the factual issue(s) in the manner sought by the person requesting the hearing would be adequate to justify the action requested. An evidentiary hearing will not be granted on factual issues that are not determinative with respect to the action requested. For example, a hearing will not be granted if the Administrator concludes that the action would be the same even if the factual issue were resolved in the manner sought.

(c) Where appropriate, the Administrator will make rulings on any issues raised by an objection which are necessary for resolution prior to determining whether a request for an evidentiary hearing should be granted.

BEFORE THE U.S. ENVIRONMENTAL PROTECTION AGENCY

COMMENTS IN OPPOSITION TO PROPOSED TOLERANCE REVOCATIONS FOR CARBOFURAN

Docket EPA-HQ-OPP-2005-0162

submitted by the

NATIONAL POTATO COUNCIL, NATIONAL CORN GROWERS ASSOCIATION, NATIONAL COTTON COUNCIL, NATIONAL SUNFLOWER ASSOCIATION, AND FMC CORPORATION

September 29, 2008

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2. **Actual Carbofuran Sales Data On A County Basis Confirm That The Actual Carbofuran PCT Is Less Than 5%, With Most PCTs Less Than 1%.**

Consistent with EPA's stated intention to use "available and reliable, representative data" for risk assessments and the SAP's recommendation to use "multiple years of data on PCT" to "modify the default assumption of 100% PCT," the registrant provided the Water Panel with actual county-level carbofuran sales data to supports its PCT estimates. These sales data were provided to EPA as part of prior reports

prepared by the Water Panel[71] and a detailed explanation of how they were analyzed, interpreted and applied was provided in Appendix B1 of the Water Panel's Best Management Practices report.[72] The Water Panel utilized the actual usage data because it represents county-level sales data carefully captured by the registrant using proven, automated techniques that are integrated into its ordinary business operations.[73] As explained in Section IV.B.5 below, assuming 5% PCT results in watershed use intensities that are 2-5 larger than the Water Panel observed in any CWSs covered by the Water Panel's National CWS Assessment in the relevant corn, sunflower and potato growing states.

The proposed tolerance revocation, on the other hand, relied on Doane or USDA/NASS data to rebut

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71 The registrant intends to resubmit a consolidated set of this data to the EPA, with an explanation of its source, on or before October 15, 2008.

72 Fawcett R.S., Engel B., and W.M. Williams (2007). Best Management Practices to Reduce Carbofuran Losses to Ground and Surface Water. MRID 47279201, Appendix B1.

73 These registrant sales data were collected from two sources: (1) the registrant's billings (known as SAP) which document the quantity of products shipped to each distributor from the company; and, (2) EDI data, which capture carbofuran sales from the distributor directly to the grower/applicator or from the distributor to retailers who then sell to growers/applicators. The registrant's comments to the SAP explain how this dealer/distributor data was dissected to isolate solely those use patterns that are being retained. *See Comments of FMC Corporation in Support of the Continued Use of Carbofuran* (Jan. 22, 2008) (EPA-HQ-OPP-2007-1088-0078.1) at 220-21 (Volume V at 11-12).

the Water Panel's PCT estimates. These data are significantly less accurate than the registrant's usage data because they are collected via grower surveys that rely on the individual growers' recollections of pesticide use. While these data are typically based on large random samples of growers and rigorous sampling and estimation methodologies, carbofuran is used by relatively few growers (e.g., it is only used on 250,000 of the 80-90 million acres of corn in the U.S.); therefore, a random sample of growers will not necessarily capture a statistically sound sample of carbofuran users. Additionally, these surveys typically have low response rates, further limiting their accuracy.[74]

The commenters recognize that the availability of county-level sales data is somewhat unusual because registrants tend to keep their usage data confidential for commercial reasons; however, that does not mean these data are unsound or inaccurate. The registrant provided such data in this instance because of the importance of developing an accurate estimate of PCT for the surface water assessments. The commenters believe that actual sales data represent the best tool for estimating watershed-level use intensity and the resultant surface water concentrations.[75]

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[74] It should also be noted that these data are intended to provide regional and crop-specific accuracy (i.e. state-level data) and are not designed to accurately capture usage for specialty products like carbofuran.

[75] "OPP may employ use data collected by the agricultural chemical industry and further make use of information from experienced extension agents in making reasonable [PCT] estimates...[A lack of PCT in modeled estimates results in]

Despite these data and the important role PCT plays in the risk estimates, the proposed tolerance revocation justifies its use of 100% PCT by: 1) comparing its surface water estimates to certain elevated concentrations observed in historical monitoring data; and 2) arguing that specific pest pressure can cause carbofuran usage to concentrate in localized areas resulting in watershed-specific elevations in PCT.[76] A closer investigation of these assertions demonstrates that neither is supportable.

### 3. Historical Concentrations Do Not Support The Use Of 100% PCT In The Surface Water Assessment.

The EPA's comparison of its surface water estimates to a specific set of historical monitoring data from Zollner Creek in Oregon is a red herring because the older data are not reflective of future carbofuran use areas and/or intensities (*i.e.*, the registrant's amended label) – which EPA itself has determined is the relevant inquiry.[77] This comparison also ignores that fact the more recent monitoring data from other

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[r]elatively high uncertainties [that] may be encountered for chemicals which are applied to less than 10% of the cropped area. FIFRA SAP, Use of Refined Watershed-Derived Percent Crop Areas as a Refinement Tool in FQPA Drinking Water Assessments for Tolerance Reassessment, p. 72 (May 25, 1999).

76 *See* 73 Fed. Reg. at 44,883-44,885.

77 2002a U.S. Environmental Protection Agency (EPA), Economic Analysis Branch, Biological and Economic Analysis Division, Office of Pesticide Programs. (2002) *Development of a Methodology for Projecting Domestic Percent Crop Treated*, http://www.epa.gov/scipoly/sap/meetings/2002/october/decisionprocess.doc at 1.

areas show that carbofuran detections are rare and at levels that are an order of magnitude lower than EPA's estimates or than were observed in Zollner Creek, an area with a unique confluence of circumstances that resulted in abnormally high carbofuran concentrations in a non-potable water body.[78]

Zollner Creek is a small, low flow, surface water body that is not, and has never been, a drinking water source. More importantly, the observed concentrations that EPA extrapolates to other use patterns (e.g., corn and sunflowers) are the result of unique circumstances related to the use patterns in the Zollner Creek watershed that are no longer on the carbofuran label. Specifically, carbofuran was once used at several nurseries and strawberry farms in the Zollner Creek watershed at estimated application rates of up 15 lbs a.i./acre (5 times higher than the maximum rate on the current label, and 15 times higher than the most common use rates).[79]

These factors demonstrate that Zollner Creek, and the detections there, are not representative of

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78 *See* 73 Fed. Reg. at 44,883; NOIC at 27.

79 The registrant voluntarily removed the strawberry and nursery use patterns from the label in 1996 and 2007, respectively, and recently prohibited all carbofuran use in most of the counties west of the Cascades Mountains in Oregon and Washington where Zollner Creek is located.

Applications at nurseries result in elevated effective use rates because they are made in concentrated container-grown nursery stock (i.e., more compound applied per area). And often these applications are made on top of plastic sheeting, creating conditions in which exaggerated levels of runoff can occur relative to runoff from a natural agricultural field.

currently labeled use patterns and do not support the use of default PCT assumptions for carbofuran. In fact, the proposed tolerance revocation notes that the "available monitoring [data] from other portions of the country suggest that the circumstances giving rise to high concentrations of carbofuran at Zollner Creek *may be rare*,"[80] yet EPA continues to use Zollner Creek to justify its elevated concentration estimates. Similarly, while EPA stresses that carbofuran has been detected in 40-100% of the annual samples collected by USGS at Zollner Creek from 1993 through 2006, and that concentrations have exceeded 1.0 ppb in 8 of 14 years with a maximum concentration of 32.2 ppb,[81] it ignores its own conclusion that the majority of concentrations detected at Zollner Creek are "in the sub-part per billion range."[82]

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80 73 Fed. Reg. at 44,883; NOIC at 27.

81 *See id.*

82 *Id.*

**BEFORE THE U.S. ENVIRONMENTAL PROTECTION AGENCY**

**OBJECTIONS TO THE FINAL ORDER REVOKING TOLERANCES FOR CARBOFURAN, AND REQUEST FOR PUBLIC EVIDENTIARY HEARING**

**74 Fed. Reg. 23,046 (May 15, 2009)**

**Docket EPA-HQ-OPP-2005-0162**

**Submitted by the**

**NATIONAL CORN GROWERS ASSOCIATION, NATIONAL SUNFLOWER ASSOCIATION, NATIONAL POTATO COUNCIL, AND FMC CORPORATION**

* * *

June 30, 2009

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OBJECTION 7: ***Carbofuran Concentrations In Drinking Water From Groundwater Sources Are Safe Because They Are Not Expected To Exceed 1.1 ppb Due To Current And Future Carbofuran Use Patterns And Label Mitigation Measures.***[43]

The Final Order concludes that expected groundwater concentrations associated with carbofuran applications would be between 0.016 and 16

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[43] For additional background information on this objection, see Petitioners' Comments at 34-36, 38- 46.

ppb. *See* U.S. Environmental Protection Agency, "Response to comments on EPA's proposed tolerance revocations for carbofuran specifically related to drinking water exposures assessment," DP 362182 (April 29, 2009) at 84 (OPP-HQ-OPP-2005-0162-0565) (the "Water Response to Comments"). Petitioners object to OPP's estimated drinking water concentrations from groundwater; the best available data supports the conclusion that carbofuran concentrations in groundwater due to use under the revised label will be less than or equal to 1.1 ppb.

**Grounds for Objection**: OPP's groundwater concentration estimates are not supported by the available data and: (1) rely on unrepresentative concentration observations for model validation from a prospective groundwater study conducted in Wicomico County, Maryland (the "PGW Study") and historical monitoring data from a period when carbofuran use was an order of magnitude larger; (2) rely on unrealistic and overly conservative assumptions about potential concentrations; (3) do not account for FMC's label mitigation measures; and (4) have been completely mitigated by the registrant's recent proposal to require setbacks of between 100 and 1,000 feet from all drinking water wells. These grounds are discussed in greater detail in the evidentiary proffer below.

**Material Issues of Fact**: (1) Whether OPP should have relied on the results of the PGW Study and historical monitoring data to validate its groundwater estimates, (2) whether the registrant's proposal to require setbacks from all drinking water wells of between 100 and 1,000 feet ensures that all potential groundwater exposures going forward are below the

level of concern. The Petitioners contend that OPP erred in calculating the estimated groundwater concentrations reported in the Final Order because those estimates relied on overly conservative assumptions that OPP attempted to validate using unrepresentative data like the PGW Study.[44] Moreover, OPP's carbofuran groundwater concentration estimates in the Final Order are inconsistent with other lower estimates relied on by OPP in the NMC Cumulative Risk Assessment. However, to provide additional assurance that potential groundwater exposures will not exceed the level of concern, the registrant has proposed to require setback of between 100 and 1,000 from all drinking water wells. Based on the foregoing, Petitioners assert that estimated groundwater concentrations will be no greater than 1.1 ppb, and that OPP's estimates are not supported by the available data. Resolution of these factual issues in the Petitioners' favor would significantly decrease the estimated carbofuran concentrations in drinking water, reducing potential exposures and causing overall carbofuran exposures from both food and water to be less than the 100% of the aPAD, making these factual issues outcome determinative and entitling the Petitioners to an evidentiary hearing.

**Evidentiary Proffer**: In support of this objection, the Petitioners intend to offer written testimony from Dr. Richard Fawcett, Dr. Bernard Engel and Mr. W.

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[44] The PGW Study was conducted in a vulnerable area that is not representative of current carbofuran use areas. All areas like the PGW Study site have been removed from the carbofuran label.

Martin Williams (the "Water Panel") demonstrating that:

- *Groundwater sources are only vulnerable to carbofuran leaching under certain conditions.*
  - Only permeable soils (e.g., greater than 90% sand and less than 1% organic matter), with acidic soil and water conditions and shallow water tables (e.g., less than 30 feet) are vulnerable to carbofuran applications.
- *Vulnerable groundwater sources are located along the eastern seaboard, and in certain counties elsewhere in the United States, all of which have been removed from the carbofuran label.*
  - Only certain soil and water types are vulnerable to carbofuran application. Work by the Water Panel has determined that these areas are limited primarily to the eastern seaboard and certain counties elsewhere in the United States. To mitigate potential exposures, carbofuran use has been precluded in these areas.
- *The available National Water Quality Assessment ("NAWQA") data indicate that carbofuran detections are rare and at low levels (i.e., less than 1 ppb), except in areas that have been labeled off because of known vulnerability.*
  - According to NAWQA data collected by the United States Geological Survey ("USGS") from 1993 through 2006 in 36 states, carbofuran was only detected in 0.74% (65) of 8,740 surveyed wells, and in almost every instance when it was detected, the observed concentrations were very low (i.e., less than

1 ppb). Moreover, since 1998 there have been no observed concentrations in the NAQWA data greater than 1.1 ppb.

- *Groundwater concentrations due to carbofuran applications are expected to be less than 1.1 ppb.*
  - The Water Panel prepared a national leaching assessment using OPP's pesticide root zone model ("PRZM"), which includes all agricultural soils in the United States, to determine potential carbofuran concentrations in those areas where carbofuran use is permitted under the revised use patterns. This assessment assumed that all aquifers are shallow (i.e., 15 feet), even though aquifers in the areas where carbofuran use is permitted are typically deeper, and looked at approximately 64,000 combinations of soil and weather patterns to develop worst case estimates of potential carbofuran concentrations in the areas where carbofuran is currently used. This assessment demonstrates, consistent with Agency practice and guidance that the expected 1-in-10 year peak concentrations are less then 1.1 ppb in the states where carbofuran use is permitted under the revised label. Potential exposures at these levels fit within the carbofuran risk cup, and are therefore safe within the meaning of the FFDCA.
  - Moreover to provide additional assurance that these estimated groundwater concentrations are conservative and will not result in concentrations that exceed the level

of concern, the registrant has proposed setbacks from all drinking water wells of between 100 and 1,000 feet (specific setback distances, based on modeling results for individual states).

- *Prevailing pH conditions in the carbofuran use states ensure the efficacy of the registrant's setbacks and that potential exposures are de minimis.*
  - o Carbofuran degrades rapidly as pH increases. At pH 7.0 carbofuran's half-life is approximately 28 days, at pH 7.5 it decreases to about a week, at pH 8.0 it is reduced to 3 days, and at pH 9.0 the half-life is only a matter of hours. In the specific regions where carbofuran will continue to be used under the revised label, groundwater pH data collected by USGS as part of the NAWQA program demonstrate that the average pH is ~7.25, and in most regions, moving two standard deviations away from the average (which would capture 95% of all observed values) results in pHs that are still greater than 6.0. Under such conditions the combination of hydrolysis and drinking water well setbacks would ensures that any carbofuran that might reach groundwater sources would have degraded to only *de minimis* concentrations less than or equal to 1.1 ppb, below the level of concern.
- *The concentrations estimated by the Water Panel's National Leaching Assessment are consistent with OPP's estimates in the NMC Cumulative Risk Assessment.*

In addition to, and in support of, the Water Panel's testimony, the Petitioners also intend to proffer the following documentary evidence:

1. Cheplick, J.M., Engel, B., Fawcett, R., Hoogeweg, C.G., and Williams, W.M., "National Carbofuran Leaching Assessment: Volume 1," (June 30, 2009) (Exhibit 12; to be submitted under separate cover);
2. Cheplick, J.M., Engel, B., Fawcett, R., Hoogeweg, C.G., and Williams, W.M., "National Carbofuran Leaching Assessment: Volume 2 – Setback Analysis," (June 30, 2009) (Exhibit 13; to be submitted under separate cover);
3. Memorandum from G. Hoogeweg and M. Williams, "Groundwater pH in selected states," (June 30, 2009) (attached as Exhibit 14);
4. Voluntary Label Amendments; and
5. In addition to the report referenced above and Petitioners' Comments on OPP's Tolerance Revocation Proposal, **Appendix C** contains a list of common references relevant to Objection 11, all of which are either (i) OPP's documents, (ii) in publicly available journals, or (iii) have already been submitted to OPP as part of the carbofuran reregistration process.

**OBJECTION 8:** ***Carbofuran Concentrations In Drinking Water From Surface Water Sources Are Safe Because They Are Not Expected To Exceed 1.1 ppb Due To Current And Future Carbofuran Use Patterns And Label Mitigation Measures.***[45]

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[45] For additional background information on this objection, see Petitioners' Comments at 46-70.

The Final Order concludes that expected surface water concentrations associated with carbofuran applications are between 4.12 and 77.6 ppb under the revised label, and that exposures at those levels are unsafe because they exceed the carbofuran risk cup. See Water Response to Comments at 83. Petitioners object to OPP's surface water estimates because they: (i) rely on unrealistic and overly conservative assumptions, and (ii) do not account for carbofuran's limited use or the registrant's voluntary cancellations and proposed label mitigation measures, carbofuran's limited PCT, or the registrant's commitment to cap the PAT for carbofuran in every watershed where it is used under the revised label at 2% on a going forward basis.

**Grounds for Objection:** OPP's conclusion that surface water exposures are between 4.12 and 77.6 ppb is not supported by the available data. OPP's surface water concentrations were developed using the PRZM/EXAMS model to estimate surface water concentrations under certain soil, water, crop and carbofuran application scenarios. These scenarios overestimate potential exposures because the surface water estimates assume that 100% of the cropped area for the modeled crop (i.e., 100% of the percent cropped area ("PCA"))[46] is treated with carbofuran. This

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[46] OPP's default percent cropped area (i.e., the proportion of a given area devoted to a particular crop) varies depending on the crop in question. For corn its 46%, for potatoes its 63% and for all other crops (e.g., sunflowers) its 87%. It should be noted that these default values – e.g., 87% PCA for sunflowers – exaggerate the PCA for many minor crops. For example, sunflowers are grown on less than 2% of the agricultural acreage (even in areas where they are an important crop).

assumption is unrealistic, and thus inappropriate for risk assessment purposes, because it does not account for the fact that carbofuran is used on less than 5% of the total acreage planted for any of the retained uses. The Final Order assumes that a 100% PCT for carbofuran is appropriate even though usage data from 2002 to present show that carbofuran usage has not exceeded 4.25% PCT in any of the watersheds where it was used during that period. Additionally, to address OPP's concern that these historical use intensities may not be representative of potential use intensities in the future, the registrant has committed to implementing a PAT cap to ensure that carbofuran cannot be used on more than 2% of the total drainage area in any watershed where its use is permitted (the "PAT Cap"). Estimating surface water concentrations based on the 2% PAT Cap demonstrates that expected carbofuran concentrations are less than or equal 1.1 ppb, a level at which drinking water exposures (both with and without food) are safe. These grounds are discussed in greater detail in the evidentiary proffer below.

**Material Issues of Fact**: Whether: (i) OPP should have incorporated more realistic estimates of PCT into its water modeling to develop more accurate estimates of potential carbofuran surface water concentrations; and (ii) OPP's estimated surface water concentrations (4.12 to 77.6 ppb) are appropriate for use in the carbofuran dietary risk assessment. Petitioners contend that OPP erred in relying on such estimates given that:

1) Carbofuran surface water concentrations are not expected to exceed ~1.1 ppb, which the Water Panel demonstrated using OPP's PRZM/EXAMS model;

2) OPP's 100% PCT assumption dramatically overestimates exposures;
3) Historical concentrations observed in NAWQA monitoring do not support OPP's surface water estimates; and
4) The Petitioners' surface water assessments are confirmed by OPP's own estimates in the NMC Cumulative Risk Assessment.

The Petitioners contend that correcting OPP's surface water concentration estimates requires the incorporation of realistic estimates of PCT into the models to reflect: (1) county-level sales data showing that carbofuran's PCT in every area where it has been used is no more than 4.25%, with most PCTs less than 1%; and (2) FMC's commitment to cap watershed PATs going forward. Resolution of these factual issues in Petitioners' favor would significantly decrease the estimated carbofuran concentrations in surface water causing overall exposures from both food and water to be less than the 100% of the aPAD, making these factual issues outcome determinative and entitling the Petitioners to an evidentiary hearing.

**Evidentiary Proffer:** In support of this objection, Petitioners intend to offer oral and written testimony from the Water Panel demonstrating that:

- *Realistic estimates of PCT must be incorporated to accurately derive estimated surface water concentrations for limited use pesticides like carbofuran; OPP's 100% PCT assumptions dramatically overestimate exposures.*
    - o Actual carbofuran sales data on a county basis from 2002-present confirm that the actual carbofuran PCT is less than 4.25%,

with most PCTs less than 1%. Under EPA's modeling approach, PCTs at this level result in an assumption that 2.0% to 3.7% of the modeled watershed's drainage area is treated with carbofuran. To ensure that these use intensity levels are maintained going forward, the registrant has committed to capping watershed-level PATs at 2.0%. The PAT Cap will ensure that potential surface water concentrations will be less than or equal to 1.1 ppb, below the level of concern.

- *Carbofuran surface water concentrations are not expected to exceed ~1.1 ppb as demonstrated by the Petitioner's PRZM/EXAMS modeling.*
  - The Petitioners prepared PRZM/EXAMS modeling utilizing the same soil, water and carbofuran application method assumptions employed by OPP, which were then adjusted to account for FMC's "no application buffers" and carbofuran's limited PCT (4.25%). After accounting for these mitigation measures, the maximum expected carbofuran concentrations were less than or equal to 1.1 ppb.
- *The registrant's prior surface water assessments did not underestimate surface water concentrations and confirm the Petitioners PRZM/EXAMS estimates.*
  - During the reregistration process, FMC submitted two different surface water studies that estimated potential exposures based on an examination of historical carbofuran use intensities and use areas. In

each instance, these observational studies concluded that carbofuran concentrations are not expected to exceed 1.1 ppb, consistent with the results of the Water Panel's PRZM/EXAMS modeling, because both the modeling and the studies represent a more realistic representation of carbofuran's PCT.

- *Contrary to OPP's suggestion, the concentrations observed in Zollner Creek, Oregon do not support OPP's drinking water assessment.*
  - The Final Order contends that the elevated surface water concentration observed in Zollner Creek, Oregon confirm the results of its surface water modeling. This conclusion is not supported by the available data because it ignores the fact that: (i) a majority of the concentrations observed in Zollner Creek were in the sub-part per billion range, (ii) the observed concentrations were the result of use patterns that are no longer on the carbofuran label and that were 5 times higher than the maximum use rate allowed under the revised label, and (iii) Zollner Creek is a small isolated creek that is not a drinking water source and, because of its size, is not representative of potential drinking water sources anywhere else.
- *Contrary to OPP's suggestion, carbofuran use patterns will not result in 100% PCT scenarios because of pest pressures.*
  - The registrant's commitment to cap watershed PAT will ensure that carbofuran use cannot exceed 2% of a given watershed's

drainage area, regardless of the pest pressures that might be present in a given area. FMC intends to enforce this PAT Cap by amending the carbofuran label to require applicators to report detailed usage information within 7 days of application, including data related to: (i) crop type, and (ii) application rate, method, timing, and location. Upon receipt of this data, the application information will be inputted into a GIS database of CWSs in the 12 States where carbofuran use is permitted under the revised label to determine, on a real time basis, what the carbofuran PAT is in each of these watersheds. As soon as any CWS hits 1.75% PAT, the registrant has committed to ceasing all carbofuran sales in any county that overlaps with such CWS for that growing season, thus ensuring that carbofuran's PAT does not exceed 2%.

- *The available NAWQA data indicate that carbofuran detections are rare in surface water, and when they occur it is at low levels (i.e., less than 1 ppb).*
  - According to NAWQA data from 1991-2006, carbofuran was only detected in 6.1% of the 20,463 samples collected. More importantly, 99.7% of those detections were less than 0.5 ppb. For the handful of detections that exceed 1.0 ppb, those detections were the result of use patterns and/or use areas that are no longer permitted under the revised label.

- *The Water Panel's surface water assessments are confirmed by OPP estimates in the NMC Cumulative Risk Assessment.*
- *In addition to its low PCT, natural surface water pH conditions in the regions where carbofuran use is permitted under the revised label ensure that potential exposures are de minimis.*
    - o Carbofuran degrades rapidly as pH increases (e.g., at pH 7.0 carbofuran's half-life is approximately 28 days, see discussion above). In the specific regions where carbofuran use will continue under the revised label, surface water pH data collected by USGS as part of the NAWQA program demonstrate that the average pH is well above 7.5, and in most regions, moving two standard deviations away from the average (which would capture 95% of all observed values) results in pHs that are still greater than 7.5. Under such conditions the limited concentrations of carbofuran that might reach surface water sources would likely not last long enough to be present in anything but *de minimis* concentrations when the water was actually supplied to the end user.
- *Similarly, pre-existing drinking water treatment systems in the regions where carbofuran is used under the revised label ensure that potential exposures are de minimis to a large proportion of the population.*
    - o A review of the existing drinking water treatment systems where carbofuran use

> continues to be permitted indicates that a majority of the large systems in those states have water treatment systems—e.g. activated carbon and lime softening—that result in the removal of 60-100% of any carbofuran that might be found. Approximately 60% of the total population in the affected states get their drinking water from surface water sources already receiving water that has been subject to either lime softening or activated carbon treatment (in some cases both), further mitigating the possibility for any exposures. It should be noted that this assessment does not mean that 40% of the population is unprotected, as a significant portion of that 40% (which are mostly rural) gets their drinking water from groundwater sources, which have already been protected by other label mitigation measures, and the remainder, to the extent they are even exposed, would be so at levels below the level of concern due to carbofuran's limited PAT and the natural surface water pH conditions occurring in those states.

In addition to, and in support of, the Water Panel's testimony, Petitioners also intend to proffer the following documentary evidence:

1. Ritter, A., Williams, W.M., "The Development and Evaluation of a Carbofuran Management Plan to Protect Drinking Water Derived from Surface Water Sources," (June 30, 2009) (Exhibit 15; to be submitted under separate cover); and

2. Memorandum from G. Hoogeweg and W.M. Williams, "Surface pH in selected states," (May 15, 2009) (attached as Exhibit 16);
3. Memorandum from W.M. Williams, "Water Treatment Assessment in Carbofuran Use States," (May 14, 2009) (attached as Exhibit 17)
4. "Petition of the National Corn Grower's Association, the National Sunflower Association, the National Potato Council, and FMC Corporation to Defer the Effective Data of Certain Tolerance Revocations for Carbofuran," (December 24, 2008) (attached as Exhibit 18) ("Deferral Petition");
5. Voluntary Label Amendments; and
6. In addition to the report referenced above and Petitioners' Comments on OPP's Tolerance Revocation Proposal, **Appendix C** contains a list of common references relevant to Objection 12, all of which are either (i) OPP's documents, (ii) in publicly available journals, or (iii) have already been submitted to OPP as part of the carbofuran reregistration process.

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OBJECTIONS EXHIBIT 1 (EXCERPTS)

FMC Corporation

Agricultural Products Group
1735 Market Street
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215 299 6000

FMC

September 29, 2008

Ms. Meredith Laws, Branch Chief
Document Processing Desk (AMEND)
Office of Pesticide Programs (RD)(7504P)
U.S. Environmental Protection Agency
One Potomac Yard, Rm. S-4900
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Arlington, VA 22202

Subject: Proposed Label Amendments
Furadan® 4F Insecticide/Nematicide
(EPA Reg. No. 279-2876)
Furadan LFR® Insecticide/Nematicide
(EPA Reg. No. 279-3310)
Furadan® 10G Insecticide/Nematicide
(EPA Reg. No. 279-2712)
Furadan® 15G Insecticide/Nematicide
(EPA Reg. No. 279-3023)

Dear Ms. Laws:

FMC is submitting the following proposed label amendments for Furadan 4F Insecticide/Nematicide and Furadan LFR Insecticide/Nematicide (collectively "flowable carbofuran") and for Furadan 10G Insecticide/Nematicide, and Furadan 15G Insecticide/Nematicide (collectively "granular carbofuran").

These label amendments include voluntary cancellations of certain carbofuran uses, pursuant to FIFRA § 6(f)(1) (7 U.S.C. § 136d(f)(1)), and new mitigation measures and use restrictions. FMC hereby waives the 180-day comment period in FIFRA § 6(f)(1)(C)(ii). The existing statutory 30-day comment period in FIFRA §6(f)(1)(B) will provide an opportunity for all interested parties, including minor crops, to provide comments. Enclosed with this letter are copies of the proposed labels, including color coded "redline" versions for ease of seeing proposed revisions, and final (black print) versions incorporating the aforementioned color coded changes.

As stated in the Agency letter (March 27, 2008), these changes should be processed as label amendments to delete uses and restrict use from certain geographical areas. Because these are considered fast-track label amendments, they will not be subject to PRIA.

The changes are reviewed in Sections (i) - (vi) hereafter.

(i) Proposed Voluntary Cancellations of "Flowable Carbofuran" Uses

FMC proposes to voluntarily cancel the following uses of flowable carbofuran pursuant to FIFRA § 6(f)(1)(A) and (B):

FIFRA § 3 Label Uses

- Alfalfa
- Cotton (at plant use only)
- Ornamentals
- Pine Seedlings (*except* in the Southeast U.S.)
- Popcorn
- Potatoes (*except* in the Pacific Northwest – Idaho, Oregon and Washington)
- Small Grains (Wheat, Oats, & Barley)
- Soybeans
- Sugarcane
- Sweet Corn
- Tobacco

FIFRA § 24 Special Local Need Label Uses

- Corn (field)
- CRP Acres
- Cucumbers
- Grapes
- Melons
- Ornamentals (container and field production)
- Peppers
- Pumpkins
- Sorghum
- Squash

- Sugar Beets
- Sugarcane (soil applied)
- Tobacco
- Wheat

In addition, FMC also proposes the voluntary cancellation, subject to a two-year phase-out period, of the following use of flowable carbofuran:

- Post-plant applications to artichokes

(ii) Retained Uses on the Proposed "Flowable Carbofuran" Labels

The following uses of flowable carbofuran are retained:

- Post-plant applications to field corn (Grain, Silage only) for corn rootworm rescue treatment
- At-plant and post-plant applications to potatoes (Idaho, Oregon, and Washington only)
- At-plant and post-plant applications to sunflowers.
- Post-plant applications to artichokes (subject to a two year phase-out)
- Applications to pine seedlings (Southeastern U.S. only)

(iii) Proposed Voluntary Cancellations of "Granular Carbofuran" Uses

FMC proposes to voluntarily cancel the following uses of granular carbofuran pursuant to FIFRA § 6(f)(1)(A) and (B):

FIFRA § 3 and § 24 Special Local Need Label Uses

- Cucumbers
- Melons
- Squash

(iv) Retained Uses on the Proposed "Granular Carbofuran" Labels

The following uses of granular carbofuran are retained:

- Pumpkin (Southeastern U.S. only)
- Applications to pine seedlings (Southeastern U.S. only)
- Spinach (grown for seed only)

(v) Additional Risk Mitigation Measures on the Proposed Labels

The proposed label includes mitigation measures that will reduce surface and groundwater exposure to carbofuran. The section entitled "Surface and Groundwater Use Restrictions" specifically enumerates these measures. FMC believes that its water assessments demonstrate that these measures (i) mitigate any potential risks posed by carbofuran to ground and surface water bodies and (ii) will ensure that all estimated drinking water concentrations resulting from any carbofuran applications will not exceed any applicable levels of concern.

(vi) Additional Label Modifications

In addition to the voluntary cancellations and mitigation measures proposed above, FMC is also making some additional changes to the Furadan 4F,

Furadan LFR, Furadan 10G, and Furadan 15G labels that fit into one of the categories below. These changes assure that general label language, use directions, use precautions and/or use restrictions are not confusing.

- Category 1: Changes in label statements and use descriptions required by the proposed deletion of certain uses.
- Category 2: Deletion/modification of label statements which are no longer applicable, and/or would be confusing.
- Category 3: Deletions of redundant precautions, restrictions, requirements which are duplicative of restrictions found in the "Surface and Groundwater Use Restriction Section" of the proposed label.

FMC is proposing the aforementioned label changes as a package of mitigation measures designed to address the potential risks posed by carbofuran. FMC believes that these mitigation measures taken together ensure that carbofuran is eligible for reregistration under FIFRA and the FQPA.

Enclosed herewith in support of this submission are the following items:

1) Completed EPA Forms 8570-1 for all "flowable" and "granular" carbofuran labels (Application for Pesticide Amendment)
2) Three copies each of the following proposed amended "flowable" and "granular" labels:
    a. Proposed label (black and white printed version)

b. Proposed label - Color coded "redline" version coded as follows: Blue type: FMC initiated general label revisions and crop use direction revisions,

Red type: FMC initiated surface and groundwater label use restrictions.

Pink type: Proposed phase-out crop uses.

Black type: Existing retained crop uses (where modifications are proposed within the existing labeled use they are presented in the redline version in blue type).

As a separate regulatory action on May 9, 2008, FMC provided the Agency a submission to supplement the pending registration amendment filed with the Agency on March 27, 1995, requesting that post-plant (foliar) applications to cotton for aphid control be added to the carbofuran label. That submission includes an application for amended registration and the associated petition to request the establishment of a tolerance for carbofuran in/on cotton by products (gin trash). Nothing in this letter is intended to modify that request and supporting submissions. FMC continues to believe that the requested foliar use on cotton meets all relevant criteria under FIFRA and FQPA and that EPA should approve the addition of that use to the Section 3 label.

Should you have any questions, or if you would like to discuss this proposal further please do not hesitate to contact me at (215) 299-6532.

Sincerely,

s/ John Cummings, Ph.D.
John Cummings, Ph.D.
Manager, North America Registration and Regulatory Affairs

cc: Debbie Edwards, OPP
Steve Bradbury, OPP/SRRD
Susan Lewis, OPP/SRRD
Jude Andreasen, OPP/SRRD
Laurel Celeste, OGC
Robert Perlis, OGC
John Hebert, OPP/RD

OBJECTIONS EXHIBIT 2 (EXCERPTS)

FMC Corporation

Agricultural Products Group
1735 Market Street
Philadelphia Pennsylvania 19103
215 299 6000

FMC

December 24, 2008

VIA EMAIL

Steve Bradbury
Deputy Office Director for Programs
Office of Pesticide Programs (7501P)
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Subject: Supplemental Label Amendments and Mitigation Measures
Furadan® 4F Insecticide/Nematicide (EPA Reg. No 279-2876)
Furadan LFR® Insecticide/Nematicide (EPA Reg. No. 279-3310)

Dear Steve:

FMC has appreciated the opportunity to meet with Agency officials over the past several weeks to discuss

carbofuran risk issues. Those discussions generated a number of constructive suggestions by the Agency for further mitigating potential risks. FMC is attempting to implement certain of those suggestions, as well as some of its own, and the purpose of this letter is to communicate the submission of our application for further registration amendments to adopt these new measures. These measures are in addition to those proposed in our September 29, 2008 amendment. They include the following:

A. Supplemental Label Mitigation Measures

FMC is proposing to further amend its September 29, 2008 labels to:

1) **Geographically limit the sunflower use pattern (both at plant and foliar)** to the states of Colorado, Kansas, Nebraska, South Dakota, North Dakota (certain counties only[1]), and Oklahoma (panhandle only)
2) Geographically limit the corn use pattern to the states of Colorado, Iowa, Illinois, Indiana, Kansas, Missouri, Nebraska, and Wisconsin (certain counties only[2]).

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[1] FMC is proposing to restrict the sunflower use pattern to the following counties in North Dakota: Adams, Barnes, Billings, Bowman, Burleigh, Cass, Dickey, Emmons, Grant, Golden Valley, Hettinger, Kidder, Lamoure, Logan, Morton, McIntosh, Sargent, Slope, Sioux, Stark, Stutsman, Ransom, and Richland.

[2] FMC is proposing to restrict the corn use pattern to the following counties in Wisconsin: Adams, Calumet, Columbia, Crawford, Dane, Dodge, Fond Du Lac, Grant, Green, Green Lake, Iowa, Jefferson, Juneau, La Crosse, Lafayette, Manitowoo, Marquette, Monroe, Richland, Rock, Sauk, Sheboygan, Vernon,

3) Impose additional mitigation measures, including requirements that aerial applicators follow the best management practices established by the National Agricultural Aviation Association.

B. **Supplemental Conditions of Registration and Mitigation Measures**

FMC is also proposing that the following additional conditions be imposed on carbofuran's registration:

1) **A two year voluntary phase out of the flowable use pattern on artichokes** consistent with the EPA's August 2006 proposal in the IRED, such that the last grower use would take place prior to December 31, 2010; and

2) **The imposition of a percent crop treated ("PCT") tracking system to ensure a community water system level PCT cap of 4 percent.** With respect to dietary risk estimates, it appears to FMC that assuring future compliance with the prior reported PCT levels would resolve the Agency's concerns under the FFDCA. In EPA's proposed tolerance revocation notice, the Agency noted the need for assurance that pesticide usage is not locally clustered in order to reduce uncertainty in the risk assessment.

In order to provide such assurance, FMC is proposing to cap carbofuran use on a watershed basis at 4 percent PCT and to enforce this cap using a PCT tracking program. By capping PCT at 4 percent, both EPA's and FMC's models will

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Walworth, Waushara, Winnebago, Washington, and the western halves of Kenosha, Racine, and Waukesha counties.

show that expected peak surface water concentrations in all watersheds (including the most vulnerable) will be less than ~1.1 ppb. Exposures at that level meet the safety standard of the FFDCA because they fit within the carbofuran risk cup, both individually and when combined with food.

FMC proposes that this cap and the PCT tracking program be imposed as a condition of carbofuran's registration/reregistration. This program will rely on point-of-sale tracking. It will require the registrant to obtain from dealers, as a condition of sale, an agreement to collect certain information from purchasers (growers and applicators), including: applicator identity, specific location of application, crop being treated, and application method. The point-of-sale data will be reported to FMC by dealers on a monthly basis. FMC will continually input the data into a GIS system that will allow FMC to determine on a watershed-by-watershed basis the total cumulative carbofuran usage (on all crops), and thus ensure that it will not exceed a PCT of 4 percent. If, as result of these monthly data, FMC determines that PCT in any given watershed exceeds 3.5 percent, FMC will immediately notify EPA and cease all sales in that watershed for the remainder of the growing season by prohibiting sales for use in any county that overlaps with the watershed in question. These PCT tracking program requirements will be enforceable against the registrant.

Further, until EPA approves this program, FMC intends to voluntarily implement the point-of-sale tracking system during the 2009 and 2010 growing seasons, and will share data with EPA annually.

FMC will be formally submitting fast track amendments to amend the applications for the subject registration consistent with the foregoing. Should you have any questions, or if you would like to discuss this proposal further, please do not hesitate to contact me at (215) 299-6532.

Sincerely,

s/ John Cummings, Ph.D.

John Cummings, Ph.D.

Manager, North America Registration and Regulatory Affairs

Cc: Debbie Edwards, OPP
Steve Bradbury, OPP
Susan Lewis, OPP/SRRD
Jude Andreasen, OPP/SRRD
Laurel Celeste, OGC
Robert Perlis, OGC
Meredith Laws, OPP/RD
John Hebert, OPP/RD

* * *

OBJECTIONS EXHIBIT 3 (EXCERPTS)

FMC Corporation

Agricultural Products Group
1735 Market Street
Philadelphia Pennsylvania 19103
215 299 6000

FMC

June 30, 2009

Ms. Meredith Laws, Branch Chief
Document Processing Desk (REGFEE)
Office of Pesticide Programs (RD)(7504P)
U.S. Environmental Protection Agency
One Potomac Yard, Rm. S-4900
2777 S. Crystal Drive
Arlington, VA 22202

Subject: Amendments to Registration (PRIA Category: R350)
Furadan® 4F InsecticidelNematicide (EPA Reg. No. 279-2876)
Furadan® LFR InsecticidelNematicide (EPA Reg. No. 279-3310)
Furadan® 10G InsecticidelNematicide (EPA Reg. No. 279-2712)
Furadan® 15G InsecticidelNematicide (EPA Reg. No. 279-3023)

Dear Ms. Laws:

FMC is submitting label amendments for Furadan 4F Insecticide/Nematicide and Furadan LFR Insecticide/Nematicide (collectively "flowable carbofuran") and for Furadan 10G Insecticide/Nematicide and Furadan 15G Insecticide/Nematicide (collectively "granular carbofuran"). While no new data is being provided with this submission, the measures included in these closely linked label amendments will require a risk analysis by the Agency's scientific divisions to support the proposed changes. As examples, the spray drift language in the flowable products may need to be reviewed by the Environmental Fate and Effects Division (EFED), and the proposed percent area treated "tracking system" may require an analysis by the Biological and Economic Analysis Division (BEAD). Therefore, FMC has determined the appropriate PRIA category for the carbofuran-containing product label amendments is **R350** with an associated fee of **$11,424.00**.

The enclosed amended labels incorporate previously submitted revisions to the Agency on September 29, 2008 and December 29, 2008 and changes, not previously submitted, in response to EPA documents supporting the May 15, 2009 final rule revoking carbofuran tolerances.

**Additional Label Mitigation Measures Proposed in this Submission**

Additional surface and ground water risk mitigation measures, not previously provided to the Agency, addressing Agency statements in the final rule announcing the revocation of carbofuran tolerances (Federal Register, Vol. 51, 5/15/09, 23046-23095) and supporting documents in docket EPA-HQ-OPP-2005-0162.

1. Percent Area Treated (%AT) Cap and Tracking System

FMC requests that EPA approve an amendment to the Furadan registration adopting an enforceable system for monitoring carbofuran usage in all watersheds in which carbofuran would be used under the revised labels. This monitoring system will be paired with an enforceable watershed-level usage cap that will keep overall usage at levels that will result in carbofuran concentrations in surface water at or below levels deemed safe. This proposal supplements the %AT monitoring system originally proposed by FMC on December 29, 2008,

In its July 31, 2008 proposed tolerance revocation, OPP determined that it could not rely on percent crop treated (%CT) estimates in modeling drinking water dietary risks, because of the alleged uncertainty in those estimates. OPP noted that in order to be protective, %CT should be assessed on a watershed scale, and %CT estimates are not available on a watershed scale with a level of certainty required to support a risk assessment.

In response, on September 29, 2008, FMC provided comments and data demonstrating that because of carbofuran's limited usage its watershed level %CT would not be expected to exceed 5% - a level that had not been exceeded in the previous decade. FMC supplemented this information on December 29, 2008 with additional label amendments proposing the adoption of a %CT tracking system that would cap carbofuran usage within every watershed where it is used at a %CT level, which the modeling demonstrates results in drinking water concentrations within each watershed that would not exceed exposure levels of 1.1 ppb.

In the May 15, 2009 final tolerance revocation rule, OPP did not respond to FMC's December 29, 2008 proposed %CT tracking amendment, presumably because it was submitted after the close of the comment period on the proposed revocation. In the final rule, OPP rejected the use of %CT estimates in part on the grounds that "it remains legally permissible for 100% of the watershed to be treated with carbofuran." 93 Fed. Reg. 23065. OPP also commented that it is "[un]aware of an enforceable mechanism to ensure that farmers applying pesticide to their fields will have the ability to determine whether a particular percentage of the watershed has been treated." *Id.* However, OPP's "major problem" with FMC's reliance on historical usage data "is that it does not appear to account for uncertainties due to variation in time and space and the potential for use to be locally concentrated due to pest pressures" in a given year in the future. *Id.* at 23066.

In recognition of these concerns and prior to the issuance of the final rule, FMC proposed to cap carbofuran usage at the watershed-level on December 29, 2008. Today's submission supplements and refines this prior proposal to provide further assurance that the specified treated acre levels are not exceeded. With the proposed %AT tracking system, it would not be "legally permissible" for 100% of a watershed to be treated with carbofuran. It would be a condition of the registration that no more than 2% of any watershed could be treated. Under the proposed amendment, the manufacturer (FMC) would be responsible for compliance with this condition, and noncompliance would constitute a violation of FIFRA.

Under this system, usage of carbofuran would be required to be reported to FMC by all applicators as a label requirement for use of the product.[1] The usage report would be required to indicate the location of the use. The usage report would be legal requirement on applicators, and noncompliance would constitute a violation of FIFRA. The usage data will be inputted into a GIS system that will enable FMC, and ultimately the Agency, to track the usage of carbofuran in every watershed on a real-time basis, so as to ensure that usage does not exceed 2% of the area in any watershed where carbofuran use is permitted. Under the amendment, should the usage in any watershed reach 1.75% FMC would be required as a condition of

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[1] It should be remembered that carbofuran is a restricted use pesticide that can only be applied by certified applicators who are very familiar with the importance of compliance with label requirements.

registration to: (1) immediately halt further sales in any county that overlaps with such a watershed, (2) recall any existing unused product in such counties, and (3) offer to buy back any existing stocks in any such county where sales are restricted under the %AT monitoring program.

The %AT tracking system would address all of the issues identified by OPP: It would eliminate all uncertainty as to the amount of usage in a watershed, providing real-time usage data to the registrant and the Agency; it would be legally enforceable against both the registrant and applicators; and it would ensure that a legally enforceable %AT cap is not exceeded in any watershed. This would provide "reasonable certainty" as to carbofuran's %AT and the safety of carbofuran residues in drinking water from surface water sources.

Terms of the amendment include:

- Tracking of usage in watersheds: In every watershed where carbofuran is used, the registrant shall track the usage on a continuing basis. The label shall provide the following requirements for reporting carbofuran usage:

  APPLICATION / USE REPORTING REQUIREMENT

  **Applicators must report application and use of this product.** Either before, or within 5 days after, application the Applicator must report to the Manufacturer the following information: the location (information provided can either be

GPS coordinates or a physical address, with the former being preferred), crop, use rate, application method, acreage, and quantity applied. The reporting of such information is mandatory and is a requirement of Federal law. Reports must be made on (URL to be added) or by calling (telephone number to be added). For questions regarding this requirement, please call (telephone number to be added).

Based on the usage information received from applicators, the registrant shall continually update the %AT in every watershed in which carbofuran is used. The registrant shall report the updated %AT data to EPA every 2 weeks during the use season, for a period of two years after this amendment to the registration is approved. Thereafter, EPA will determine with what frequency such information should be reported for future years. The registrant shall maintain such usage records for a period of five years.

- Usage cap: Whenever the %AT for carbofuran reaches 1.75% in a watershed, the registrant shall immediately report such information to EPA, shall cease further sales in any county that overlaps with such a watershed for that use season, and shall attempt to recall all unused carbofuran within such counties by offering to repurchase such unused product.

- Allocations to distributors: Based on the watershed boundaries, the registrant shall, prior

> to each use season, allocate carbofuran to its distributors in a manner which will attempt to ensure that no distributor receives more carbofuran for sale than can be accommodated by the 2% watershed area cap in any watershed supplied by that distributor.

While OPP appears to have taken the position that the proposed %AT amendment should not be considered, we do not believe that OPP can revoke carbofuran tolerances on the grounds that there is no enforceable mechanism that would ensure that %AT levels are not exceeded, and then simply ignore proposed registration amendments that would remedy that problem. Therefore, FMC requests OPP to consider this amendment in good faith and determine whether it will effectively ensure that drinking water exposures will be maintained at safe levels.

2. State-wide Drinking Water Well Setbacks

FMC proposes additional ground water mitigation measures requiring 100 - 1000 feet setbacks from all drinking water wells in geographies where carbofuran may be used. The proposal to implement "state-wide" drinking water well setbacks is overly conservative given the infrequent geographic occurrence of vulnerable soil conditions where potential exposure is possible. However, for ease of implementation, the state wide restrictions are proposed.

3. Additional Geographic Restrictions for the Potato Use

As an additional refinement to limiting the potato use to the three Pacific Northwest states (ID, OR, and WA), FMC proposes to further limit potato use in Washington to seven potato producing counties where vulnerable surface and ground water conditions are not present.

4. Use of Granular Carbofuran Products on Pumpkins

FMC has revised the geographic restrictions and directions for use on pumpkins. Based on recent sales data, the use of carbofuran products on pumpkins occurs primarily in the states of IL, IN, OH, and MI. As the proposed label prohibits use in Michigan, the pumpkin use is proposed for the states of OH, IL, and IN only. Surface water and groundwater label restrictions in those states are applicable to this use pattern. The target pests have been revised to be consistent with special local need labels and reflective of current use. To address the Agency's statements on the pumpkin use rate in the final tolerance revocation and supporting documents, the use directions have been clarified and the rates have been reduced for the granular products to more accurately reflect the typical use of the product and to ensure the rates will result in acceptable risk calculated using the Agency's drinking water models.

5. Use of Flowable Carbofuran Products on Sunflowers

FMC has added a use restriction prohibiting any foliar applications to sunflowers, if an at-plant application was made to that sunflower crop. Additionally, a limit of one foliar application per season has been proposed. Both measures will alleviate the Agency's concern raised in the final tolerance revocation rule and supporting documents.

6. Environmental Hazard Statements

All flowable and granular carbofuran products have been revised to incorporate the most recent Agency label guidance for environmental hazard statements relating to surface water, groundwater, and bee toxicity.

7. Surface and Groundwater Use Restrictions on Granular Product Labels

All granular carbofuran product labels have been revised to incorporate the corresponding language on the flowable product labels relating to surface and groundwater restrictions. EPA correctly identified the inconsistency in the response to FMC comments.

8. Carbofuran Products—Special Local Need Labels

EPA identified label inconsistencies between the amended labels (9/29/08) and currently approved Special Local Need (SLN) labels for flowable carbofuran. FMC agrees that the approved SLN labels in the states of Oregon (OR910006, OR910007) and Idaho (ID910007, ID060003) contain use directions inconsistent with the proposed amended labels. FMC

will contact the regulatory authorities in these states to request labels be amended prohibiting the use of flowable carbofuran products in areas with soils greater than 90% sand and less than 1% organic matter), acidic soil and water conditions (e.g., pH less than 7.0), and shallow water tables predominate (e.g., where the water table (groundwater) is less than thirty feet). In addition, revised language will be provided to state regulators to ensure consistency in the maximum application rate for the at plant potato use (3 lb ai/A). As FMC has limited the use of flowable carbofuran products to Idaho, Oregon, and Washington, FMC will contact the state of Colorado requesting the cancellation of SLN CO920001.

**Additional Label Mitigation Measures Proposed in 12/29/08 Submission**

Additional surface and ground water risk mitigation measures provided in the December 29, 2008 non-PRIA fast track amendment submission resulting from discussions between the registrant and EPA. Despite FMC submitting these additional proposed mitigation measures more than four months prior to the tolerance revocation final rule publication (May 15, 2009), the Agency did not consider the measures in their definitive risk assessments forming the basis of their final tolerance revocation decision. The only response received from the Agency was that the submission did not formally qualify as a non-PRIA fast track amendment.

Please refer to the FMC letter (Cummings to Laws, 12/29/08) for complete details.

- Geographically limit the sunflower use pattern (both at plant and foliar) to the states of Colorado, Kansas, Nebraska, South Dakota, North Dakota (limited counties only), and Oklahoma (panhandle only)

- Geographically limit the corn use pattern to the states of Colorado, Iowa, Illinois, Indiana, Kansas, Missouri, Nebraska, and Wisconsin (limited counties only).

- Requiring aerial applicators to follow the best management practices established by the National Agricultural Aviation Association.

- A two year voluntary phase out of the flowable use pattern on artichokes consistent with the EPA's August 2006 proposal in the IRED

Additional Label Mitigation Measures Proposed in 9/29/08 Submission

Additional surface and ground water risk mitigation measures included in the September 29, 2008 non-PRIA fast track amendment. These risk mitigation measures were considered, in part, by EPA with Agency responses provided in the final rule announcing the revocation of carbofuran tolerances (Federal Register, Vol. 51, 5/15/09, 23046-23095) and supporting documents in docket EPA-HQ-OPP-2005-0162.

Please refer to the FMC letter (Cummings to Laws, 9/29/08) for complete details.

- Prohibiting flowable carbofuran use on the entire east coast of the US to address EPA

concerns in geographies with vulnerable drinking water sources from surface water and groundwater.

- Prohibiting flowable and granular carbofuran use in numerous counties throughout the US to address EPA concerns in geographies with vulnerable drinking water sources from surface water and groundwater.
- Non-application buffers (ground and aerial application) from water bodies in certain geographies to address EPA concerns with vulnerable drinking water sources from surface water and groundwater.

**Label Changes from Voluntary Cancellation Proposed in 9/29/08 Submission (4)**

Label changes resulting from FMC's voluntary cancellation of certain uses of flowable and granular carbofuran which was submitted September 29, 2008 as part of a non-PRIA fast track amendment and approved in the Agency's final cancellation order (Federal Register, Vol. 51, 3/18/09, 11551-11553).

Please refer to the FMC letter (Cummings to Laws, 9/29/08) for complete details.

- Removal of flowable carbofuran uses consistent with final cancellation order: alfalfa, cotton (at plant use only), ornamentals, pine seedlings (*except* in the Southeast U.S.), popcorn, potatoes (*except* in the Pacific Northwest – Idaho, Oregon and Washington), small grains (wheat, oats, & barley), soybeans, sugarcane, sweet Corn, tobacco, CRP acres, cucumbers, grapes, melons,

peppers, pumpkins, sorghum, squash, sugar beets.

- Removal of granular carbofuran uses consistent with final cancellation order: cucumbers, melons, squash

Enclosed herewith in support of this submission are the following items:

- Completed EPA Forms 8570-1 for the subject "flowable" and "granular" carbofuran labels (Application for Pesticide Amendment)
- Three copies each of the proposed amended "flowable" and "granular" labels:
    - The red highlighted text includes proposed label changes made in the December 29, 2008 submission (not considered by the Agency to date) and new changes proposed with this submission).

Should you have any questions, or if you would like to discuss this proposal further please do not hesitate to contact me at (215) 299-6532.

Sincerely,

s/ John Cummings, Ph.D.
John Cummings, Ph.D.
Manager, North America Registration and Regulatory Affairs

cc: Debbie Edwards, OPP
Rick Leigwin, OPP/SRRD
Laura Parsons, OPP/SRRD
Jude Andreasen, OPP/SRRD
Laurel Celeste, OGC
Robert Perlis, OGC
John Hebert, OPP/RD

* * *

OBJECTIONS EXHIBIT 13 (EXCERPTS)

## STUDY TITLE

National Carbofuran Leaching Assessment
Volume 2 - Setback Analysis

## REQUIREMENT

Not Applicable

## AUTHORS

W.M. Williams, J.M. Cheplick, B. Engel, R. Fawcett,
and C.G. Hoogeweg

## COMPLETION DATE

July 1, 2009

## PERFORMING LABORATORIES

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REPORT NUMBER

WEI 528.01-C
FMC # PC-0461

SUBMITTER/SPONSOR

FMC Corporation
1735 Market Street
Philadelphia, PA 19103

* * *

# National Carbofuran Leaching Assessment: Volume 2 - Setback Analysis

## 1.0 Executive Summary

The groundwater well setback distances discussed in this report are part of a management plan to mitigate the potential for carbofuran to occur in drinking water above levels of concern. Carbofuran, 2,3-dihydro-2,2-dimethyl-7-benzofuranylmethylcarbamate, is the active ingredient in Furadan® 4F, LFR, 10G and 15G, carbamate insecticides developed by FMC Corporation (FMC). This study builds on a series of other drinking water exposure assessments (Fawcett et al., 2007a; 2007b; 2007c; Williams et al., 2009) that have been conducted for carbofuran. Collectively, these

assessments have led to significant modifications to carbofuran's use patterns as well as label restrictions, including labeling off areas with potentially vulnerable groundwater, removing a majority of uses from the carbofuran label and the drinking water well setbacks discussed in this report. These restrictions are outlined in three label amendment letters (collectively, the "Revised Label") that have been submitted to the U.S. Environmental Protection Agency's (USEPAs) Office of Pesticide Programs (OPP).[1]

One of the prior assessments was a National Carbofuran Leaching Assessment (NCLA) that was conducted to predict potential carbofuran concentrations in shallow groundwater (Williams et al., 2009). The assessment used the Pesticide Root Zone Model (PRZM) to simulate the leaching of carbofuran residues at a depth of 5 m for all agricultural soils in the United States. Daily predictions of water and chemical leaching through a 5 m soil depth were further processed by an aquifer model to calculate daily concentrations of carbofuran in shallow groundwater. The 90th percentile acute concentration estimate, calculated from the annual maximum series, was used for risk assessment purposes. The 90th percentile concentration corresponds to a 1-in-10 year return period and is consistent with OPP procedures. The

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[1] Letter from J. Cummings, FMC Corporation ("FMC") to M. Laws (EPA) regarding Proposed Label Amendments dated September 29, 2008; Letter from J. Cummings (FMC) to S. Bradbury (EPA) regarding Supplemental Label Amendments and Mitigation Measures dated December 24, 2008; and Letter from J. Cummings (FMC) to M. Laws (EPA) regarding Amendments to Registration dated June 30, 2009.

prior assessment indicated that carbofuran concentrations in the remaining use areas were below the applicable levels of concern, and was used to develop additional geographic restrictions to prohibit application in areas of the country that are potentially vulnerable to carbofuran leaching. As a results of the NCLA, additional states and counties were removed from the carbofuran label such that the 90th percentile area-weighted EDWC in the remaining use areas did not exceed the level of concern (1.1 ppb). These geographical restrictions were submitted to OPP in September 2008 (the "September 2008 label").[1] A concentration of 1.1 ppb was used as the level of concern because dietary risk assessments prepared for carbofuran have concluded that drinking water concentrations at this level are safe – i.e., they fit within the carbofuran risk cup (Barraj et al., 2009).

Despite the results of the NCLA, the setback analysis reported herein was conducted to alleviate concerns expressed by OPP that the NCLA may not have been sufficiently protective because: (1) not all potential use patterns were modeled, and (2) the geographic and soil property restrictions on FMC's September 2008 label might not have addressed potential exposures in all locations in the United States where groundwater concentrations might be of concern (USEPA 2009;

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[1] Letter from J. Cummings, FMC Corporation ("FMC") to M. Laws (EPA) regarding Proposed Label Amendments dated September 29, 2008; Letter from J. Cummings (FMC) to S. Bradbury (EPA) regarding Supplemental Label Amendments and Mitigation Measures dated December 24, 2008; and Letter from J. Cummings (FMC) to M. Laws (EPA) regarding Amendments to Registration dated June 30, 2009.

Jones et al. 2009). To eliminate these concerns, setback distances were calculated for all geographical areas remaining on the Revised Label[2] to ensure that maximum, not 90th percentile, concentrations were below 1.1 ppb.

Similar to the prior NCLA, this assessment utilized PRZM to simulate the leaching of carbofuran residues at a depth of 5 m. Daily predictions of water and chemical leaching through a 5-m soil depth were further processed by an aquifer model to calculate daily concentrations of carbofuran in shallow groundwater. The 90th percentile acute concentration estimates were used for risk assessment purposes. Unlike the previous assessment, all soils were simulated including those classified by the USDA as non-agricultural soils. The geographic area studied was limited to the carbofuran use areas expressly identified on the revised label.

Well setback distances · were calculated using procedures developed by OPP for aldicarb as part of the NMC cumulative risk assessment and for carbofuran in the Final Tolerance Revocation. Assumptions on groundwater flow velocity of 0.15 m/day were consistent with those used by OPP.

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[2] These areas include a portion of the Corn Belt (Colorado, Iowa, Illinois, Indiana, Kansas, Missouri, Nebraska, and certain counties in Wisconsin); the Pacific Northwest (Oregon, Idaho and Washington); portions of the High Plains where sunflowers are grown (Colorado, Kansas, Nebraska, South Dakota and certain counties in North Dakota and Oklahoma); and three states in the Midwest (Ohio, Indiana, and Illinois) for carbofuran use on pumpkins (granular only).

Degradation rates for carbofuran in the modeled aquifer varied by state as a function of the state-specific groundwater pHs developed as part of this report. These pHs were based on the lower 95th percentile of pH values measured in a given state, thereby providing a conservative estimate of carbofuran persistence in groundwater.

The reasonable worst-case setback distances calculated for the Carbofuran Use States under the Revised Label ranged from approximately 50 to 1,000 feet as shown in the table below.

**Setback distance (ft) by State (Ag and Non-Ag Soils and without soil texture restrictions)**

| State | CO | IA | ID | IL | IN | KS | MO | ND |
|---|---|---|---|---|---|---|---|---|
| Setback | *35* | *1028* | *35* | *187* | *236* | *37* | *212* | *91* |
| **State** | **NE** | **OH** | **OK** | **OR** | **SD** | **WA** | **WI** | |
| Setback | *91* | *85* | *0* | *284* | *91* | *225* | *74* | |

Model simulations assumed all acreage in the carbofuran use area would receive applications of carbofuran at the maximum permitted application rate for 30 consecutive years. Modeled estimates used to generate the setbacks included both agricultural and non-agricultural soils, and only excluded the soil textures expressly removed from the carbofuran label. Further, model predictions assume that all application sites are underlain by a shallow aquifer at a depth of 5 m with a pH value equal to the lower 95th percentile of measured values in a given state.

Many areas indicated as having relatively high concentrations would not be as vulnerable as indicated in this study because aquifers used for drinking water would typically be considerably deeper and significant additional retardation of water, pesticide flux, and degradation of carbofuran would occur in these areas.

Additionally, a very limited amount of acreage in a given state is likely to receive applications. Carbofuran use has decreased tremendously in the past 20 years from general use on a variety of crops to more limited use on a specialized group of crops. Moreover, the registrant has committed to capping the percent area treated in any community water system watershed where carbofuran is used. This cap provides certainty that carbofuran usage will be very low going forward, despite the fact that chemical use can also vary from year-to-year due to crop rotations and pest pressures. By ensuring limited usage in all areas where carbofuran use might occur, FMC provides additional assurance that the potential for carbofuran leaching to groundwater is very low, further ensuring conservatism in these estimates related to potential variations in carbofuran usage.

* * *

OBJECTIONS EXHIBIT 15 (EXCERPTS)

## STUDY TITLE

The Development and Evaluation of a Carbofuran Management Plan to Protect Drinking Water Derived from Surface Water Sources

## DATA REQUIREMENT

Not Applicable

## AUTHOR

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## COMPLETION DATE

July 1, 2009

## PERFORMING LABORATORY

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## REPORT NUMBER

WEI 528.01-D

FMC # PC-0462

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* * *

## EXECUTIVE SUMMARY

Carbofuran, 2,3-dihydro-2,2-dimethyl-7-benzofuranylmethylcarbamate, is the active ingredient in Furadan® 4F, LFR and 15G, a carbamate insecticide developed by FMC Corporation (FMC). The U.S. Environmental Protection Agency's Office of Pesticide Programs (OPP) prepared drinking water exposure estimates for the use of carbofuran on corn, sunflowers, potatoes, pumpkin, pine seedlings, artichoke, and spinach grown for seed in August 2008. Estimated drinking water concentrations (EDWC) predicted by OPP were updated in April 2009. Carbofuran fate and transport were estimated using the Pesticide Root Zone Model (PRZM), Version 3.12, which simulated chemical application, dissipation, and runoff mass of carbofuran from a watershed. Carbofuran residues, as predicted by PRZM, provided loadings to OPP's "index reservoir" scenarios, which were modeled using the Exposure Analysis Modeling System (EXAMS), Version 2.98.04.

This report refines the modeling work OPP completed on carbofuran and evaluates the efficacy of the mitigation measures being proposed by the registrant (FMC) to protect surface water drinking supplies, including: (i) substantial crop and geographical restrictions on how and where carbofuran can be used; (ii) imposing a cap on the percent area treated (PAT) in any watershed where carbofuran use is permitted under the revised label; and (iii) buffer strips to minimize the transport of carbofuran to surface water sources.

The study was performed following OPP procedures for a Tier 2 risk assessment with refinements added to evaluate the efficacy of the aforementioned mitigation measures. Estimated drinking water concentrations (EDWCs) were predicted using OPP's "index reservoir" with the PRZM/EXAMS models. Use patterns addressed herein include potatoes (in Idaho and specific areas in Washington, and Oregon); corn (in Iowa, Missouri, Kansas, Nebraska, and specific areas in Wisconsin, Illinois, and Indiana); sunflowers (in Colorado, South Dakota, Kansas, Nebraska, and specific areas in North Dakota and Oklahoma); and pumpkins (in Ohio and specific areas in Illinois and Indiana). Ten index reservoir scenarios were selected and/or developed to represent these use patterns.[1] Applications of carbofuran were simulated to occur at maximum label rates under the application methods

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[1] OPP does not have standard scenarios for sunflowers or pumpkins in the revised carbofuran use area and therefore, scenarios developed by OPP for other crops in this area were adapted for this assessment to represent sunflowers and pumpkins.

specified on the revised label. Environmental fate parameters for carbofuran were identical to those used by OPP in their drinking water assessments for carbofuran.

Surface water concentrations predicted by PRZM/EXAMS were multiplied by OPP's appropriate regional percent crop area (PCA) factor and then multiplied by a 4.25% percent crop treated (PCT) factor. The PCA multiplied by the PCT is the percent area treated (PAT) (the percent of total area in the modeled watershed treated with carbofuran). Resulting PAT values ranged from 1.96% to 3.7% among the scenarios, which compare to a maximum actual PAT value of 1.5% determined from a national assessment of the relative vulnerability of community water supply reservoirs in carbofuran use areas.[2] This indicates that the surface water concentrations predicted using a 4.25% PCT are adequately conservative.

For model scenarios exceeding an acute EDWC of 1.1 ppb, setback buffers were evaluated as a mitigation measure to reduce both drift and runoff loadings of carbofuran to drinking water sources. The value 1.1 ppb was provided by the registrant (FMC) as a safe limit in drinking water after accounting for potential dietary residues from food.

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[2] The national assessment of the relative vulnerability of community water supply reservoirs in carbofuran use areas was based on carbofuran use data from 1998 to 2003. This period is prior to the revised label and at a time when carbofuran use was more widespread (Fawcett et al., 2007; Williams et al., 2007).

Two of the modeled scenarios (Kansas corn and Kansas sunflowers with aerial applications) had an acute EDWC exceeding 1.1 ppb. The Kansas corn scenario had the highest acute EDWC of 1.43 ppb. These scenarios were rerun with progressively increasing cropped buffer strips (66, 125, and 300 feet) until the modeled EDWCs were below 1.1 ppb. The buffers were simulated as a cropped-buffer strip as opposed to a vegetated filter strip because cropped buffers are the simplest for growers to implement, particularly those needing to make post-plant applications. This analysis determined that 300-ft cropped-buffers would be required for aerial applications on corn and sunflowers in Kansas to ensure EDWCs less than 1.1 ppb.

Upper 10th Percentile Concentrations in Water

| Crop Scenario | Buffer (ft) | Type of Buffer | Application Type | Field and Buffer Curve Numbers | Drift onto Reservoir % | PCA | Peak Acute (µg/L) | |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | 100% PCT | 4.25% PCT |
| IL Corn | — | None | Aerial | 91 87 91 | 16 | 0.46 | 16.58 | 0.70 |
| IN Corn | — | None | Aerial | 91 84 91 | 16 | 0.46 | 17.23 | 0.73 |
| ID Potato | — | None | Ground | 89 86 89 | 6.4 | 0.63 | 4.86 | 0.21 |
| WA Potatoe | — | None | Ground | 91 89 91 | 6.4 | 0.63 | 10.81 | 0.46 |
| OH Pumpkin | — | None | Ground | 91 89 91 | 0 | 0.87 | 0.74 | 0.03 |

| Crop Scenario | Buffer (ft) | Type of Buffer | Application Type | Field and Buffer Curve Numbers | Drift onto Reservoir % | PCA | Peak Acute (µg/L) | |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | 100% PCT | 4.25% PCT |
| KS Sunflower | — | None | In-furrow | 94 88 94 | 0 | 0.87 | 15.44 | 0.66 |
| | | | | | | | | |
| NE Sunflower | — | None | In-furrow | 94 88 94 | 0 | 0.87 | 12.97 | 0.55 |
| | | | | | | | | |
| NE Corn | — | None | Aerial | 94 88 94 | 16 | 0.46 | 22.24 | 0.94 |
| | | | | | | | | |
| KS Corn | — | None | Aerial | 94 88 94 | 16 | 0.46 | 33.57 | 1.43 |
| KS Corn | 66 | Crop | Aerial | 94 88 94 | 7.2 | 0.46 | 32.55 | 1.38 |
| KS Corn | 125 | Crop | Aerial | 94 88 94 | 4.8 | 0.46 | 30.21 | 1.28 |
| KS Corn | 300 | Crop | Aerial | 94 88 94 | 2.6 | 0.46 | 25.74 | 1.09 |

| Crop Scenario | Buffer (ft) | Type of Buffer | Application Type | Field and Buffer Curve Numbers | Drift onto Reservoir % | PCA | Peak Acute (µg/L) | |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | 100% PCT | 4.25% PCT |
| KS Sunflower | — | None | Aerial | 94 88 94 | 16 | 0.87 | 31.78 | 1.35 |
| KS Sunflower | 66 | Crop | Aerial | 94 88 94 | 7.2 | 0.87 | 30.82 | 1.31 |
| KS Sunflower | 125 | Crop | Aerial | 94 88 94 | 4.8 | 0.87 | 28.59 | 1.22 |
| KS Sunflower | 300 | Crop | Aerial | 94 88 94 | 2.6 | 0.87 | 24.36 | 1.04 |

To demonstrate the conservatism in these EDWCs, a sensitivity analysis was preformed to evaluate the impact of tillage practices on surface water runoff. Tillage practices have a pronounced impact on surface water runoff because they directly affect the quantity of crop residue left on the field (more crop residue means less runoff). This sensitivity analysis was conducted using the Nebraska corn scenario and compared reduced and no-till to conventional tillage practices. Acute EDWCs were reduced 36 and 62 percent relative to conventional tillage, respectively, with the addition of reduced tillage and no-till practices. Since no-till and reduced tillage practices have become much more common as a result of USDA's soil conservation programs, this analysis suggests that the EDWC estimates presented in this report will typically be conservative as they assume conventional tillage practices are employed.

Based on the analysis contained within this report, and the previous assessments cited herein (Fawcett et al., 2007; Williams et al., 2007), the following mitigation measures are recommended to protect community water supplies with surface water sources from exceeding carbofuran concentrations of 1.1 ppb:

- Limiting carbofuran use to the crops, geographical areas, application methods, and application rates proposed by the registrant on the revised label;

- Developing and enforcing a stewardship program that limits carbofuran use within a drinking water supply's drainage area to 2.0% of the contributing drainage area; and,

- Requiring 66-ft buffers everywhere (except Kansas where 300-ft buffers are required) to adjacent water bodies for aerial applications of carbofuran to corn and sunflowers.

* * *

OBJECTIONS EXHIBIT 18

## PETITION OF THE NATIONAL CORN GROWER'S ASSOCIATION, THE NATIONAL SUNFLOWER ASSOCIATION, THE NATIONAL POTATO COUNCIL, AND FMC CORPORATION TO DEFER THE EFFECTIVE DATE OF CERTAIN TOLERANCE REVOCATIONS FOR CARBOFURAN

* * *

### IV. REASONS WHY DEFERRAL OF TOLERANCE REVOCATION IS WARRANTED

In the case of carbofuran, the petitioners believe that the situation falls within the latter category. That is, there is not so much a dispute over whether carbofuran poses a health risk as much as whether the proof of its safety is sufficiently incontestable so as to meet the "reasonable certainty of no harm" standard. In such a situation, we believe that continuation of the specified tolerances until the dispute has been resolved is warranted and appropriate.

First, carbofuran is not a new chemical. It has been in use for four decades. During this entire period, there has never been an indication of an actual health threat from the dietary ingestion of carbofuran residues.

Second, the amount of carbofuran that is proposed to be continued to be used, during the period of a hearing, is a small fraction of the historical use levels. Future carbofuran use is estimated at 200,000 pounds a

year—down from peak usage of 10,000,000 pounds a year.

Third, the majority of the remaining usage is restricted to 11 states, with only very minor quantities being applied outside of those states.

Fourth, there are only a few minor "niche" uses for which the tolerances are proposed to be retained. In each instance, carbofuran remains important to growers in these niche use patterns because it provides unique pest control benefits. Indeed, for the corn and sunflower use patterns, carbofuran is the only alternative. Thirty-two other use patterns have been voluntarily cancelled.

Fifth, and perhaps most important, when we run the risk assessment numbers *using almost all of EPA's own assumptions*, including EPA's point of departure and EPA's proposed safety factors, we find that these *retained tolerances still fit within the risk cup*. There would appear to be no debate that, using EPA's own assumptions, dietary (food only) exposures fit within the risk cup. With respect to drinking water exposures, the disagreement between EPA and the petitioners turns mostly on whether there is adequate assurance that the historic "percent crop treated" (PCT) numbers supplied by FMC will hold for future use to ensure that drinking water exposures do not exceed levels of concern. To provide such assurance, FMC has proposed the PCT tracking program described below as a condition for registration.

Sixth, FMC will implement immediately, for the 2009 growing season, a point of sale usage tracking system, which will provide the requisite degree of assurance for the PCT numbers; and FMC will cap usage within every watershed at those PCT levels, and

immediately stop sales in any watershed where the PCT begins to approach the levels that assure safety.

Finally, we note that public comments made by EPA managers confirm that no imminent hazard to human health from continued carbofuran use is expected ("Bradbury said that the pesticide residues are in such small concentrations that they would rarely pose a risk, but that they could if certain foods were eaten in combination.")[3] With the voluntary use cancellations and PCT program FMC is adopting, any "rare" risk would be vanishingly small to non-existent.

In short, we can provide assurance that, using EPA's own assumptions, there will not be an imminent health risk during the period that it will take to resolve the petitioners' objections. Since there is not a risk of actual adverse effects during the hearing process, the disputed tolerances should remain in effect pending a final decision as to whether the requisite degree of "certainty" of safety has been satisfied.

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[3] "In Surprise Move, EPA Bans Carbofuran Residue on Food," *Washington Post* (July 25, 2008) (A-Section, p. A02). Jim Gulliford is also quoted as stating that carbofuran doesn't meet "our high standards" and that "while there is little exposure today [to the pesticide], we don't think there's a need, a reason for any exposure." *Id.* No immediate health risk was cited by EPA as a reason for the tolerance revocation.

FILED
APR 25 2011
OFFICE OF THE CLERK

No. 10-1031

# In the Supreme Court of the United States

NATIONAL CORN GROWERS ASSOCIATION, ET AL.,
PETITIONERS

*v.*

ENVIRONMENTAL PROTECTION AGENCY, ET AL.

*ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT*

## BRIEF FOR THE RESPONDENTS IN OPPOSITION

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## QUESTION PRESENTED

Whether the Environmental Protection Agency reasonably determined that it was not "necessary" (21 U.S.C. 346a(g)(2)(B)) to conduct an evidentiary hearing concerning the safety risk posed by a particular pesticide, after the agency concluded that petitioners' submissions in support of a hearing did not comply with the agency's procedural rules and did not create a genuine issue of material fact.

TABLE OF CONTENTS

Page

Opinions below ..... 1
Jurisdiction ..... 1
Statement ..... 2
Argument ..... 14
Conclusion ..... 28

TABLE OF AUTHORITIES

Cases:

*AFL-CIO* v. *Chao*, 409 F.3d 377 (D.C. Cir. 2005) ..... 23
*Advocates for Hwy. and Auto Safety* v. *Fed. Motor Carrier Safety Admin.*, 429 F.3d 1136 (D.C. Cir. 2005) ..... 22
*Chase Bank USA, N.A.* v. *McCoy*, 131 S. Ct. 871 (2011) ..... 21
*Chevron U.S.A. Inc.* v. *NRDC, Inc.*, 467 U.S. 837 (1984) ..... 21
*Community Nutrition Inst.* v. *Young*, 773 F.2d 1356 (D.C. Cir. 1985), cert. denied, 475 U.S. 1123 (1986) ... 13
*Hynson, Westcott & Dunning, Inc.* v. *Richardson*, 461 F.2d 215 (4th Cir. 1972), aff'd as modified, 412 U.S. 609 (1973) ..... 24
*Kreis* v. *Secretary of the Air Force*, 866 F.2d 1508 (D.C. Cir. 1989) ..... 23
*Pactra Indus., Inc.* v. *CPSC*, 555 F.2d 677 (9th Cir. 1977) ..... 26
*Puerto Rico Aqueduct & Sewer Auth.* v. *EPA*, 35 F.3d 600 (1st Cir. 1994), cert. denied, 513 U.S. 1148 (1995) ..... 24
*Sims* v. *Apfel*, 530 U.S. 103 (2000) ..... 21

Page

Cases—Continued:

*United States* v. *L.A. Tucker Truck Lines*, 344 U.S. 33 (1952) ..... 21

*Universal Health Servs., Inc.* v. *Thompson*, 363 F.3d 1013 (9th Cir. 2004) ..... 22

*Vermont Yankee Nuclear Power Corp.* v. *NRDC*, 435 U.S. 519 (1978) ..... 12, 20

*Webster* v. *Doe*, 486 U.S. 592 (1988) ..... 23

*Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609 (1973) ..... 25

Statutes and regulations:

Federal Food, Drug and Cosmetic Act, 21 U.S.C. 301 *et seq.*:

21 U.S.C. 331(a) (Supp. II 2009) ..... 2

21 U.S.C. 342(a) ..... 2

21 U.S.C. 346a (2006 & Supp. II 2009) ..... 2

21 U.S.C. 346a(b)(2)(A)(i) ..... 2

21 U.S.C. 346a(b)(2)(A)(ii) ..... 2

21 U.S.C. 346a(b)(2)(C)(i)(II) ..... 2

21 U.S.C. 346a(b)(2)(C)(i)(III) ..... 2

21 U.S.C. 346a(e)-(g) ..... 3

21 U.S.C. 346a(e)(1)(A) ..... 2

21 U.S.C. 346a(e)(2) ..... 19

21 U.S.C. 346a(g) ..... 3, 14

21 U.S.C. 346a(g)(2) ..... 13

21 U.S.C. 346a(g)(2)(A) ..... 3, 23, 25, 26, 27

21 U.S.C. 346a(g)(2)(B) ..... 3

21 U.S.C. 346a(g)(2)(C) .....

Statutes and regulations—Continued: Page

21 U.S.C. 355(e) ..... 25
21 U.S.C. 371(e) ..... 26
Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136 *et seq.*:
7 U.S.C. 136a(a) ..... 3
7 U.S.C. 136j(a)(2)(G) ..... 4
5 U.S.C. 553 ..... 19
5 U.S.C. 706 ..... 23
21 C.F.R. 130.14(b) (1972) ..... 25
40 C.F.R.:
Section 178.32(b) ..... 3
Section 178.32(b)(2) ..... 23, 24

Miscellaneous:

*Carbofuran; Final Tolerance Revocations*, 74 Fed. Reg. (2009):
p. 23,046 ..... 4
p. 23,047 ..... 5, 6, 8
pp. 23,048-23,049 ..... 4
p. 23,060 ..... 6, 7
pp. 23,061-23,062 ..... 11
p. 23,061 ..... 8, 16
p. 23,062 ..... 8
p. 23,065 ..... 6
p. 23,066 ..... 6, 7, 10, 14
p. 23,068 ..... 7
p. 23,071 ..... 4

Miscellaneous—Continued: Page

p. 23,084 ..... 7
Carbofuran; Proposed Tolerance Revocations,73 Fed. Reg. (2008):
pp. 44,864-44,865 ..... 17
p. 44,864 ..... 5, 8
p. 44,865 ..... 5, 8, 12, 17
p. 44,866 ..... 5
59 Fed. Reg. 33,684 (1994) ..... 27
73 Fed. Reg. 42,683 (2008) ..... 27
75 Fed. Reg. 55,997 (2010) ..... 27

# In the Supreme Court of the United States

No. 10-1031

NATIONAL CORN GROWERS ASSOCIATION, ET AL.,
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*v.*

ENVIRONMENTAL PROTECTION AGENCY, ET AL.

*ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT*

## BRIEF FOR THE RESPONDENTS IN OPPOSITION

### OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-15a) is reported at 613 F.3d 266. The orders of the Environmental Protection Agency (Pet. App. 16a-342a, 343a-368a, 369a-376a) are reported at 74 Fed. Reg. 59,608 (2009), 74 Fed. Reg. 23,046 (2009), and 73 Fed. Reg. 44,864 (2008).

### JURISDICTION

The judgment of the court of appeals was entered on July 23, 2010. A petition for rehearing was denied on October 19, 2010 (Pet. App. 381a). On December 28, 2010, the Chief Justice extended the time within which to file a petition for a writ of certiorari to and including February 16, 2011, and the petition was filed on that

date. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

## STATEMENT

1. a. The Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 *et seq.*, directs the Environmental Protection Agency (EPA) to ensure that pesticide residues on foods distributed to American consumers are safe. See generally 21 U.S.C. 346a (2006 & Supp. III 2009). The FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue," including exposures through drinking water. 21 U.S.C. 346a(b)(2)(A)(ii).

The FFDCA requires EPA to establish "tolerances"—the maximum level of a pesticide residue allowed in or on food. 21 U.S.C. 346a (2006 & Supp. III 2009). Without a tolerance (or an exemption), food containing pesticide residues is considered unsafe and thus "adulterated," meaning that it cannot be legally distributed in interstate commerce. 21 U.S.C. 342(a); see 21 U.S.C. 331(a) (Supp. III 2009). EPA must revoke or modify a tolerance if the agency determines it is not "safe." 21 U.S.C. 346a(b)(2)(A)(i). In deciding whether to revoke a tolerance, EPA must separately evaluate the risk a pesticide poses to infants and children, by considering, *inter alia*, "the special susceptibility of infants and children to the pesticide chemical residues" and "the cumulative effects on infants and children of such residues." 21 U.S.C. 346a(b)(2)(C)(i)(II) & (III).

The statute establishes a multi-step process for the revocation of a tolerance. 21 U.S.C. 346a(e)-(g). EPA must first publish a proposed revocation rule and generally must provide a 60-day public comment period. 21 U.S.C. 346a(e)(2). After considering comments sub-

mitted during that period, EPA issues a final rule. 21 U.S.C. 346a(e)(1)(A).

After the agency has issued a final rule, any person may file objections with EPA "specifying with particularity the provisions of the regulation or order deemed objectionable" and may request an evidentiary hearing on those objections. 21 U.S.C. 346a(g)(2). The FFDCA states that EPA shall "hold a public evidentiary hearing if and to the extent the Administrator determines that such a public hearing is necessary to receive factual evidence relevant to material issues of fact raised by the objections." 21 U.S.C. 346a(g)(2)(B).

EPA regulations state that the agency will hold a hearing only if it "determines" that the material submitted by the requestor shows that (1) there is "a genuine and substantial issue of fact" for resolution at a hearing; (2) there is "a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor" of the requesting party; and (3) the resolution of the factual issues in the manner sought by the requesting party "would be adequate to justify the action requested." 40 C.F.R. 178.32(b). If a person files objections, EPA must issue a final order separately stating the action taken on each objection and whether any hearing is appropriate. 21 U.S.C. 346a(g)(2)(C).

b. EPA also regulates pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* While the FFDCA authorizes the establishment of legal limits for pesticide residues in food, FIFRA requires EPA approval of pesticides prior to their sale and distribution, and it establishes a registration regime that regulates the use of pesticides. 7 U.S.C. 136a(a). FIFRA also requires EPA to review

and approve pesticide labels, and it provides that use of a pesticide inconsistent with its label is illegal. 7 U.S.C. 136j(a)(2)(G).

2. EPA has classified the pesticide carbofuran as "Toxicity Category I, the most toxic category, based on its potency by the oral and inhalation exposure routes." *Carbofuran; Final Tolerance Revocations*, 74 Fed. Reg. 23,046, 23,071 (2009) (*Final Rule*). Carbofuran causes inhibition of the enzyme acetylcholinesterase, and such inhibition can result in "prolonged stimulation of nerves and muscles." *Ibid.* Among the symptoms of carbofuran poisoning are "headache, nausea, dizziness, blurred vision, excessive perspiration, salivation, lacrimation (tearing), vomiting, diarrhea, aching muscles, and a general feeling of severe malaise." *Ibid.* "Severe poisoning can lead to convulsions, coma, pulmonary edema, muscle paralysis, and death by asphyxiation." *Ibid.* Carbofuran poisoning can also lead to neurological and psychological symptoms, such as "confusion, anxiety, depression, irritability, mood swings, difficulty concentrating, short-term memory loss, persistent fatigue, and blurred vision." *Ibid.* Carbofuran has a "steep dose-response curve," meaning that "small differences in human exposure levels can have significant adverse consequences for large numbers of individuals." *Ibid.*

a. In 2006, EPA completed a dietary risk assessment for carbofuran that "showed acute dietary risks from carbofuran residues in food above EPA's level of concern." *Final Rule*, 74 Fed. Reg. at 23,048-23,049. In May 2008, petitioner FMC Corporation (FMC), which markets carbofuran, offered to modify its registration to "cancel" all use of the chemical on certain crops. Under the proposed modification, FMC would have adopted use restrictions to "mitigate" water contamination on re-

maining uses, in exchange for EPA's agreement to "permit the retention of several uses that do not meet the FFDCA * * * safety standard or the FIFRA registration standard." *Carbofuran; Proposed Tolerance Revocations*, 73 Fed. Reg. 44,864, 44,866 (2008) (*Proposed Rule*). EPA declined the offer, and FMC withdrew it. *Ibid.*

On July 31, 2008, EPA proposed to revoke all tolerances for carbofuran on the ground that aggregate exposures from all uses of carbofuran are not "safe." *Proposed Rule*, 73 Fed. Reg. at 44,864; see *id.* at 44,866 ("[U]nder every analysis EPA has conducted, the levels of carbofuran exceed the safe daily dose for children, even when EPA used the most refined data and models available. Based on these findings, EPA has decided to move as expeditiously as possible to address the unacceptable dietary risk to children."). The *Proposed Rule* advised parties that if they "anticipate[d] that [they] may wish to file objections to the final rule, [they] must raise those issues in [their] comments on this proposal." *Id.* at 44,865; see *id.* at 44,864 ("Issues not raised during the comment period may not be raised as objections to the final rule, or in any other challenge to the final rule."). EPA emphasized that it would "treat as waived, any issue not originally raised in comments on this proposal." *Id.* at 44,865.

b. On September 29, 2008 (the date comments were due on the proposed tolerance revocation), FMC asked EPA to cancel carbofuran's registration under FIFRA for 28 crops. *Final Rule*, 74 Fed. Reg. at 23,047. At the same time, FMC "indicated that it no longer seeks to maintain the tolerances associated with the domestic use of carbofuran on the eliminated crops, and therefore no

longer opposes the revocation of those tolerances." *Ibid.* EPA accordingly revoked the tolerances. *Ibid.*

At the same time, FMC sought to retain EPA tolerances for two "national food uses," corn and sunflowers, and "two regional food uses," potatoes in the Northwest and pumpkins in the Southeast. *Final Rule*, 74 Fed. Reg. at 23,060. EPA concluded, however, that continued use of the chemical even in that limited manner was not safe because its "analyses show that those individuals—both adults and children—who receive their drinking water from sources vulnerable to carbofuran contamination are exposed to carbofuran levels that exceed EPA's level of concern—in some cases by orders of magnitude." *Id.* at 23,047; see *ibid.* (explaining that "estimates for aggregate food and ground water exposure" ranged from 780% of the safe dose for adults over age 50 to 9400% of the safe dose for infants); see also *id.* at 23,060.

FMC had submitted "assessments that relied in part on what [it] refer[ed] to as 'county-level usage data'" in an effort to have EPA's exposure model replace its assumption of 100% use of carbofuran in cropped areas with a much lower figure. *Final Rule*, 74 Fed. Reg. at 23,066; see *id.* at 23,065. EPA "agree[d] [with FMC] that county-level use data would be useful in generating reasonable estimates of [the percentage of crops treated (PCT)] that could be used in drinking water assessments." *Id.* at 23,066. The agency found, however, that the material FMC had provided was unreliable for two independent reasons.

First, rather than providing actual "usage data," FMC had provided "estimates" that the company apparently had derived from sales data. *Final Rule*, 74 Fed. Reg. at 23,066. FMC declined, however, to provide the "'actual sales data' [it] used to develop these estimates,

or the methods used to estimate county level usage from the sales data." *Ibid.* "In the absence of the data or [such] analyses * * *, EPA [was] unable to verify or evaluate the results of any analyses that rely on these data and [could] reach no conclusion on its validity or utility." *Ibid.*

Second, FMC's methodology (to the extent EPA could discern it from the company's incomplete submissions) did not "appear to account for uncertainties due to variation in time and space and the potential for use to be locally concentrated due to pest pressures." *Final Rule*, 74 Fed. Reg. at 23,066. EPA explained that, because "pesticide use varies from year to year, and can in some cases be patchy, with high levels of use in small areas and little use in most areas," FMC's methodology could result in "substantial" underestimation of the percentage of crops treated in "small watersheds." *Ibid.*

Notwithstanding the inadequacy of FMC's data, EPA performed a "sensitivity analysis" to determine whether lowering the assumed percentage of crops treated below 10% would "meaningfully affect the outcome of the risk assessment." *Final Rule*, 74 Fed. Reg. at 23,068. The agency concluded that "use of a reasonably conservative [percentage of crops treated] estimate, even if one could be developed, would not meaningfully affect the carbofuran risk assessment, as aggregate exposures would still exceed 100%" of the safe daily dose. *Ibid.*; see *id.* at 23,084.

As part of their comments, petitioners also "summariz[ed] * * * the results" of a "national leaching assessment" that "they claim[ed] to have conducted" regarding the soil and water conditions that would and would not lead to carbofuran contamination of ground water. *Final Rule*, 74 Fed. Reg. at 23,060. Petitioners

did not, however, submit the assessment itself. *Ibid.* EPA therefore was unable to evaluate the assessment's "methodology" or "whether the assessment actually support[ed] [petitioners'] claims." *Id.* at 23,061 ("Based on the information provided, EPA cannot confirm or negate the assertion that there is no overlap between use and all potentially vulnerable ground water, as the information provided does not enable the Agency to evaluate this claim."); *id.* at 23,062 (EPA unable to "determine model input parameters or check model algorithms" based on limited information provided by petitioners).

EPA advised interested parties that they could file objections to the *Final Rule*, while stating (as it had in the *Proposed Rule*) that "the substance of the objection must have been initially raised as an issue in comments on the proposed rule." *Final Rule*, 74 Fed. Reg. at 23,047; see *Proposed Rule*, 73 Fed. Reg. at 44,864, 44,865. Accordingly, EPA warned parties that it "[would] treat as waived any issue not originally raised in timely submitted comments." *Final Rule*, 74 Fed. Reg. at 23,047.

c. On June 29, 2009, FMC proposed yet again to amend carbofuran's FIFRA registration, this time to adopt, *inter alia*, a novel scheme relying on post-application monitoring by FMC of pesticide usage in an attempt to limit carbofuran usage to two percent of a watershed. Pet. App. 112a. FMC also proposed geographic restrictions on carbofuran's use, additional crop restrictions, and set-back requirements. *Id.* at 113a. On the same day, petitioners filed objections to the *Final Rule* and requested an evidentiary hearing. *Id.* at 21a. Petitioners' objections were "based on the FIFRA registration amendments that FMC filed" simultaneously

with its comments, *i.e.*, "45 days after the safety determination was made." *Id.* at 22a; see *id.* at 78a (explaining that petitioners' objections were "inextricably intertwined with proposed changes to carbofuran's FIFRA registration that were not submitted until after publication of the final tolerance revocation rule").

On November 18, 2009, EPA denied Petitioners' objections and hearing requests on several independent grounds. Pet. App. 16a-342a. First, EPA determined that, under settled administrative procedure, petitioners could not "challeng[e] EPA's safety determination based on proposed FIFRA registration changes not before EPA at the time of its final revocation decision." *Id.* at 22a. EPA noted that FMC was free to continue its pursuit of the proposed FIFRA registration amendments and then, if EPA accepted them, request the reestablishment of carbofuran tolerances based on the new registration. *Id.* at 22a-23a; see *id.* at 86a. The agency explained, however, that FMC could not require EPA to "shoot at a moving target, much less a target that is not in existence," by proposing to limit the pesticide's adverse impact only after EPA had made its final determination. *Id.* at 85a ("Petitioners are actually not objecting to the conclusions in the EPA's final rule; rather, they are suggesting that EPA might reach a different result in a different factual scenario."); see *id.* at 78a, 114a-115a; 310a-311a.

EPA further concluded that, even aside from the inappropriate use of the untimely registration proposal, petitioners had not properly joined issue with the conclusions the agency had announced in the *Final Rule*. Pet. App. 23a. Petitioners had repeatedly failed to respond to the agency's "detailed determinations" in the *Final Rule*, instead merely filing "recycled comments on

the proposed rule." *Id.* at 23a-24a. The *Final Rule* had responded to the points made in the earlier comments, yet petitioners had simply refiled those comments without attempting to articulate how the agency had erred in its responses. *Id.* at 23a; see *id.* at 73a, 78a-79a, 312a.

Petitioners had also repeatedly attempted to rely on untimely-filed submissions and had failed to submit supporting documents that would have allowed the agency to evaluate petitioners' empirical claims. Pet. App. 23a. For example, EPA explained that FMC had "failed to provide the data and details" or the "critical components that served to support key inputs" of "an alternate risk analysis purporting to show that aggregate carbofuran exposures to children would be safe." *Id.* at 73a. Without that information, EPA "was unable to accept the validity or utility of the analyses, let alone rely on the results." *Id.* at 74a.

In EPA's view, petitioners' request for a hearing on the percentage of crops treated was illustrative of the flaws in their overall approach. In denying petitioners' objections to the agency's use of a 100% treatment assumption, the agency reiterated its view that "county-level use data would be useful in generating reasonable estimates of PCT that might be appropriately used in drinking water assessments." Pet. App. 238a. EPA explained, however, that petitioners had offered no such data. *Ibid.* In their comments on the proposed revocation, petitioners had instead offered an analysis apparently derived from *sales* data (although petitioners had not timely submitted the underlying data themselves). In the *Final Rule*, EPA had explained at length why such sales data were inadequate and unreliable. *Id.* at 232a; see *Final Rule*, 74 Fed. Reg. at 23,066; see also Pet. App. 238a-240a (discussing the "two major prob-

lems in equating sales information with use information"). In their hearing request, however, petitioners had "not responded to EPA's explanation in the final rule of the reasons that the information and methodology on which they relied to estimate a four percent PCT was flawed." *Id.* at 232a. Instead, petitioners had "ignored EPA's extensive analysis of this issue in the final rule and simply refiled their comments on the proposal as if EPA's determination in the final rule did not exist." *Id.* at 233a; see *id.* at 330a.

EPA determined as well that, in making their hearing request, petitioners had relied on several forms of untimely-submitted material. During the comment period, petitioners had failed to submit the "modeling" or the underlying sales data, even though both were available to them at that time. Pet. App. 233a-234a; see *id.* at 330a. Moreover, to the extent petitioners' request for a hearing was based on a purported factual issue about PCT created by the "risk mitigation measures" included in the proposed revision of their FIFRA registration, that claim was not properly before the agency. *Id.* at 234a, 330a.

EPA applied a similar analysis to petitioners' handling of the "National Leaching Assessment." Petitioners had failed to submit that assessment itself with their comments to the proposed revocation, instead relying on only a summary that was inadequate to be evaluated. Pet. App. 209a-210a (citing *Final Rule*, 74 Fed. Reg. at 23,061-23,062). Petitioners had belatedly submitted a version of the Assessment along with their hearing request. EPA explained that "[b]ecause the National Leaching Assessment was available during the comment period but was withheld, this information is considered to be untimely and the [p]etitioners have waived the

right to rely on it." *Id.* at 210a. In addition, because petitioners had modified the Assessment to account for FMC's belated proposed registration amendments, it also did not provide a proper basis for objecting to the *Final Rule* issued before those amendments were offered. *Id.* at 210a-211a.

3. Petitioners filed a petition for review in the court of appeals, which denied it in relevant part. Pet. App. 1a-15a.

a. With respect to petitioners' challenge to the agency's use of a 100% PCT, the court of appeals noted that the agency had declined to consider arguments and information that had not been timely filed during the comment period before the *Final Rule*. Pet. App. 7a-8a. The court rejected petitioners' contention that they had a right under the FFDCA to "rais[e] in [their] objections issues that could have been but were not raised in the comments." *Id.* at 8a. The court noted that EPA has "broad discretion to 'fashion [its] own rules of procedure' in order to implement the multi-stage procedures required by the FFDCA," and that it was a proper exercise of that discretion to require "issues to be raised at the first available opportunity." *Ibid.* (quoting *Vermont Yankee Nuclear Power Corp.* v. *NRDC*, 435 U.S. 519, 544 (1978)). The court explained that EPA had consistently enforced that requirement and, in the *Proposed Rule*, had "specifically reminded parties interested in the present proceeding of the practice." *Ibid.* (citing 73 Fed. Reg. at 44,865). Without this requirement, the court explained, "the comment period would be redundant and superfluous," and a party would have no "incentive to raise an issue at the comment stage if it could wait without prejudice to see whether doing so was still necessary at the objection stage." *Id.* at 8a-9a.

The court of appeals further held that EPA had properly declined "to consider any of petitioners' arguments based upon" FMC's proposed registration amendments because that proposal had been submitted after issuance of the *Final Rule*, and "[o]bjections that assumed the amendments had been or would be accepted by the agency were not responsive." Pet. App. 11a. The court also concluded that EPA had properly declined petitioners' hearing request based on their "recycled" comments. *Id.* at 10a-11a. The court noted that a hearing request "must be directed 'with particularity [to] the provisions of the [final rule] deemed objectionable.'" *Id.* at 11a (brackets in original) (quoting 21 U.S.C. 346a(g)(2)(A)). By ignoring EPA's reasons for rejecting their comments previously, the court explained, petitioners had "failed to lodge a relevant objection." *Ibid.*

b. The court of appeals concluded that EPA had properly denied petitioners' request for a hearing on the question "whether carbofuran will be applied in areas with soil that is 'vulnerable' to the carbofuran leaching into the groundwater." Pet. App. 12a-13a. The court explained that, because petitioners had failed to timely submit the study on which they based their argument, the agency had properly rejected it. *Id.* at 13a. The court of appeals also observed that, even if the study had been properly before the agency—thus creating a "dispute between experts"—the court would not reverse an agency's finding that "there is no material issue of fact" based on "[m]ere differences in the weight or credence given to particular scientific studies." *Ibid.* (quoting *Community Nutrition Inst.* v. *Young*, 773 F.2d 1356, 1363 (D.C. Cir. 1985), cert. denied, 475 U.S. 1123 (1986)).

## ARGUMENT

The court of appeals' affirmance of EPA's decision not to hold an evidentiary hearing turned on proceeding-specific facts and circumstances and does not conflict with any decision of this Court or another court of appeals. This case would be a poor vehicle for examination of the legal standard for invocation of the FFDCA's hearing provision because both the hearing denial and the court of appeals' affirmance of it were largely based on petitioners' serial waivers and failures to comply with standard rulemaking procedural requirements. In any event, EPA's rejection of petitioners' hearing request was fully consistent with all applicable statutory and regulatory requirements. Further review is not warranted.

1. Contrary to petitioners' contention (Pet. 16), this case does not present the question whether 21 U.S.C. 346a(g)(2) requires EPA to conduct a hearing when there is "a bona fide dispute among experts over material facts." Pet. 16. Petitioners do not identify any "expert" (Pet. 16) opinion that could have created a legitimate factual dispute in this case. In particular, petitioners' challenge to EPA's assumption of a 100% crop treatment percentage did not create such a dispute. EPA agreed with FMC that reliable "county-level use data would be useful in generating reasonable estimates of [the percentage of crops treated] that could be used in drinking water assessments." *Final Rule*, 74 Fed. Reg. at 23,066. Petitioners did not submit any such data, however. They instead submitted an analysis based on *sales* data, but failed to timely submit those data or adequately explain the methodology they had used to derive usage estimates from them. *Ibid.* In the *Final Rule*, EPA explained in detail why it could not rely on petition-

ers' inadequately-explained analysis of the sales data. *Ibid.* Instead of responding to that refutation of their analysis, petitioners' hearing request simply resubmitted their prior contentions. Pet. App. 232a-233a.

In declining to hold a hearing to determine the percentage of crops treated with carbofuran, EPA thus did not find petitioners' proffered "expert" opinion on a factual question less persuasive than some other "expert" opinion. Instead, EPA found that petitioners had failed to submit any expert opinion directly addressing the relevant question. Accordingly, in the absence of any reliable data supporting a lower figure, the agency adhered to its assumption of 100% crops treated "due to the large uncertainties in the actual PCT on a watershed-by-watershed basis." Pet. App. 235a. EPA agreed that "[i]n most cases, * * * it is unlikely that 100% of the crop will be treated with a single pesticide in most watersheds, particularly in larger watersheds." *Id.* at 235a-236a. It nevertheless found that, "for small watersheds, it is reasonable to assume that an extremely high percentage of the crops in the watershed may be treated." *Id.* at 236a. Petitioners' inadequate submissions failed to create any "bona fide" dispute concerning that assumption.

The court of appeals' analysis of this question was likewise based on petitioners' procedural lapses. In affirming EPA's decision to deny a hearing on the percentage of crops treated with carbofuran, the court upheld the agency's conclusions that petitioners' empirical submissions were "untimely and forfeited" (Pet. App. 8a), and that their "recycled" comments failed entirely

to "address[] the responses EPA had made to them in" the *Final Rule* (*id.* at 10a-11a).[1]

There was also no "bona fide dispute" between experts regarding "whether carbofuran will be applied in areas with soil that is 'vulnerable' to the carbofuran leaching into the groundwater." Pet. App. 12a. Petitioners' claims in that regard were based on the conclusions they attributed to a "National Leaching Assessment." *Final Rule*, 74 Fed. Reg. at 23,061. EPA concluded, however, that it was not able to "confirm or negate" petitioners' contentions based on the Assessment because petitioners had failed to submit the Assessment to the agency for review. *Ibid.* Petitioners belatedly submitted the Assessment (modified to account for FMC's intervening proposal to amend carbofuran's registration) with their request for a hearing. Pet. App. 210a. Because the Assessment "was available during the comment period but was withheld," however, EPA concluded that petitioners' submission was "untimely." *Ibid.* The court of appeals affirmed EPA's waiver finding on groundwater, concluding that the agency had "properly refused to consider" the National Leaching Assessment because it "could have been but was not submitted with the petitioners' [c]omments" on the *Proposed Rule*. *Id.* at 13a.[2]

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[1] Only after concluding that the hearing denial was supported by petitioners' procedural failures did the court of appeals briefly note that, "[i]n any event," EPA had not "abused its discretion in concluding the petitioners failed to present sufficient evidence to warrant using a PCT lower than 100 when estimating concentrations of carbofuran in surface water." Pet. App. 11a.

[2] The court of appeals' subsequent statement that it would not "overturn" EPA's determination that no material issue of fact existed despite petitioners' claim of a "dispute between experts" was thus unnecessary

In sum, both EPA's denial of a hearing in this case, and the court of appeals' affirmance of that decision, rested independently on the agency's findings that petitioners had failed to properly present the data and arguments they attempted to advance in support of their hearing request. Cf. Pet. C.A. Br. 19 (acknowledging that in denying the hearing request, EPA had placed "overwhelming reliance" on waiver findings).

2. Petitioners contend that EPA improperly relied on a "novel rule * * * categorically to reject objections as either 'too early' or 'too late.'" Pet. 14; see Pet. 26-31. Contrary to petitioners' contentions, EPA properly applied longstanding waiver and exhaustion principles to the circumstances of this case, and nothing in the agency's analysis warrants this Court's review.

a. At the outset of the proceeding, EPA warned petitioners and other potential commenters that if they "anticipate[d] that [they] may wish to file objections to the final rule, [they] must raise those issues in [their] comments on this proposal." *Proposed Rule*, 73 Fed. Reg. at 44,865. The agency also stressed that "[i]ssues not raised during the comment period may not be raised as objections to the final rule, or in any other challenge to the final rule," and that "EPA will treat as waived, any issue not originally raised in comments on this proposal." *Id.* at 44,864-44,865.

In disregard of those warnings and the ordinary exhaustion principles they reflect, petitioners failed to submit the studies and data on which they attempted to rely in their comments on the proposed revocation. When

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and was, at most, an alternative to its principal holding that EPA had "properly refused to consider" the National Leaching Assessment because it was untimely filed. Pet. App. 13a.

EPA explained in the *Final Rule* that petitioners' decision to withhold relevant information had prevented the agency from evaluating their claims, petitioners belatedly submitted the missing information along with their hearing request. By that time, however, it was too late. Just as EPA had stated it would do, it treated claims based on untimely submitted information as waived.

Likewise, petitioners' hearing request repeatedly relied on "recycled" comments that petitioners had submitted before EPA issued the *Final Rule*. Pet. App. 10a. In the *Final Rule*, EPA explained at length why it had rejected the contentions made in petitioners' comments. Rather than responding to that analysis, petitioners mechanically resubmitted the same comments as if EPA's findings did not exist. The problem was not that petitioners had submitted the comments "too early." Cf. Pet. 14. Rather, those resubmitted comments were unsuited to the task at hand because they were wholly unresponsive to the specific agency decision (the *Final Rule*) to which they were nominally offered as objections.

Petitioners' resubmitted comments might roughly be analogized to a petition for rehearing en banc that simply incorporates portions of a party's earlier brief to the panel, without discussing the panel's analysis or attempting to explain why it is wrong. It is neither unfair nor logically inconsistent to require that a rehearing petition must specifically identify the alleged flaws in the panel opinion (and in that respect must be meaningfully different from the party's brief to the panel), while precluding the assertion of wholly new arguments (except to the extent that the panel decision raises new issues that the party had no prior opportunity to address, cf. note 3, *infra*). The same is true here.

b. Petitioners contend that they had an unqualified right under the FFDCA and EPA's regulations to object to a final revocation on any basis at all, whether or not they had properly preserved the contention at the comment stage of the proceeding. Pet. 27-29. Petitioners identify no court of appeals that has adopted that reading of the statute and implementing regulations, and EPA properly rejected it.

As EPA explained, the hearing provision in 21 U.S.C. 346a(g) is "part of a coherent statutory structure inextricably linked to the FFDCA's informal rulemaking procedures and section 553 of the [Administrative Procedure Act (APA) ]." Pet. App. 88a. As petitioners conceded before the agency, Section 346a "establishes an informal rulemaking process" governed by 5 U.S.C. 553, and it is settled that "the failure to raise factual or legal issues during the comment period of a rulemaking constitutes waiver of the issues in further proceedings." Pet. App. 88a. Although the FFDCA "in certain limited circumstances supplements the informal rulemaking with a hearing," it "does not fundamentally alter the requirements applicable to informal rulemakings." *Id.* at 90a. The rulemaking phase of the proceeding is designed "to resolve the issues that can be resolved, and to identify and narrow any remaining issues for adjudication." *Ibid.*

The subsequent phase where a party may request a hearing "does not represent an unlimited opportunity to supplement the record, particularly with information that was available during the comment period, but that commenters have chosen to withhold." Pet. App. 90a. EPA explained that acceptance of petitioners' contrary view—under which a party could submit any evidence and contentions as part of a request for a hearing, un-

hindered by any waiver rules—would "render the rulemaking portion of the process entirely duplicative of the hearing, and thus, ultimately meaningless." *Id.* at 91a. Accordingly, EPA explained, the agency had for years consistently enforced the rule that parties could not withhold evidence or contentions during the comment phase and then raise them for the first time when requesting a hearing. *Id.* at 93a-94a.

While acknowledging that the FFDCA "provides little guidance on the objections that a party may raise," the agency concluded that "the relative silence of the statutory provision does not mean that EPA is required to allow parties to raise any and all objections; rather it means that Congress left the question of what constitutes 'reasonable grounds' for EPA to resolve." Pet. App. 92a. It was "undeniably a reasonable exercise of discretion to ensure that the rulemaking is not an opportunity for one party to waste the time and resources of all parties—both the government and other rulemaking participants—by failing to raise all of their issues or withholding information for the purpose of surprising the government at a later point during the proceeding." *Id.* at 93a.

"Absent constitutional constraints or extremely compelling circumstances the administrative agencies should be free to fashion their own rules of procedure and to pursue methods of inquiry capable of permitting them to discharge their multitudinous duties." *Vermont Yankee Nuclear Power Corp.* v. *NRDC*, 435 U.S. 519, 543 (1978) (internal quotation marks and citation omitted). No such "extremely compelling circumstances" (*ibid.*) are present in this case, where EPA simply applied a commonplace requirement of administrative exhaustion. See *United States* v. *L.A. Tucker Truck*

*Lines*, 344 U.S. 33, 37 (1952) ("[A]s a general rule * * * courts should not topple over administrative decisions unless the administrative body not only has erred, but has erred against objection made at the time appropriate under its practice."). Moreover, EPA's interpretations of both the FFDCA and the agency's own implementing regulations are entitled to deference, see *Chevron U.S.A. Inc.* v. *NRDC*, 467 U.S. 837, 843 (1984); *Chase Bank USA, N.A.* v. *McCoy*, 131 S. Ct. 871, 880 (2011), and petitioners fail to demonstrate that their contrary reading is compelled by the statutory or regulatory text.[3]

c. The court of appeals' affirmance of EPA's application of its waiver rule in this case does not conflict with any decision of this Court or another court of appeals. Petitioners' reliance (Pet. 30) on *Sims* v. *Apfel*, 530 U.S. 103 (2000), is misplaced. That case involved procedures specific to the Social Security Act that were "inquisitorial rather than adversarial" and in which the reviewing administrative body did "not depend much, if at all, on claimants to identify issues for review." *Id.* at 111-112 (opinion of Thomas, J.). In FFDCA tolerance rulemakings, by contrast, normal administrative-exhaustion re-

[3] EPA did not, as petitioners contend (Pet. 28), rely on its waiver rules to bar petitioners from raising issues or evidence at the hearing stage that responded to changes in EPA's reasoning between the *Proposed* and *Final Rules*. As explained above, EPA's analysis of the PCT issue did not change between the *Proposed Rule* and the *Final Rule*. On groundwater, EPA used the same modeling in the *Final Rule* that it had in the *Proposed Rule*; the only modification in the analysis was the one required by FMC's proposal to restrict use of carbofuran to limited geographic areas. A change in the scope of analysis required by a party's own decision to withdraw use of its product from many parts of the country does not constitute "a new rationale." *Ibid.*

quirements are appropriate because the interested parties are responsible for identifying and developing the issues that the agency is to resolve. For that reason, the courts of appeals have generally held that *Sims* is not applicable to administrative rulemaking proceedings. See *Advocates for Hwy. & Auto Safety* v. *Federal Motor Carrier Safety Admin.*, 429 F.3d 1136, 1149 (D.C. Cir. 2005); *Universal Health Servs., Inc.* v. *Thompson*, 363 F.3d 1013, 1020 (9th Cir. 2004) (*Sims* "turned on the unique nature of the Social Security benefit proceedings and offers no guidance relevant to rulemaking.").

The Third and Ninth Circuit decisions on which petitioners rely (Pet. 30-31) do not conflict with the decision in this case because none of them addressed a two-step administrative process analogous to proceedings under the FFDCA. The court below found EPA's waiver procedure reasonable specifically because it ensured that both steps of the tolerance-revocation process were meaningful. Pet. App. 8a-9a. Moreover, petitioners were explicitly warned about the waiver rule from the outset of the proceeding. Under those circumstances, there is no support for petitioners' contention that other courts of appeals would have disapproved EPA's application of its longstanding waiver rules.

3. Even if EPA's denial of petitioners' hearing request were not independently justified by petitioners' serial waivers, this case would present no question warranting further review.

a. The FFDCA requires EPA to "hold a public evidentiary hearing if and to the extent the Administrator determines that such a public hearing is necessary to receive factual evidence relevant to material issues of fact raised by the objections." 21 U.S.C. 346a(g)(2)(B); see 40 C.F.R. 178.32(b)(2) ("An evidentiary hearing will

not be granted * * * if the Administrator concludes that the data and information submitted, even if accurate, would be insufficient to justify the factual determination urged."). A statutory provision like this one, triggered by a finding that something is "'necessary' * * * is an inherently discretionary standard that clearly invites further definition by the [agency]." *AFL-CIO* v. *Chao*, 409 F.3d 377, 393 (D.C. Cir. 2005) (Roberts, J., concurring in part and dissenting in part) ("Determining what is 'necessary' unavoidably calls for the exercise of the [agency's] judgment and expertise.").

Under the FFDCA's plain language, moreover, a hearing is required only "if and to the extent *the Administrator determines* that such a public hearing is necessary." 21 U.S.C. 346a(g)(2)(B) (emphasis added). Reviewing courts have distinguished between statutory requirements that depend on "the objective existence of certain conditions," and those that are based on an agency's "determination that such conditions are present." *AFL-CIO*, 409 F.3d at 393 (Roberts, J., concurring in part and dissenting in part) (quoting *Kreis* v. *Secretary of the Air Force*, 866 F.2d 1508, 1513 (D.C. Cir. 1989)). A "statute phrased in the latter terms fairly exudes deference" to the agency. *Ibid.* (internal quotation marks and citation omitted); see *Webster* v. *Doe*, 486 U.S. 592, 600 (1988).

Particularly in light of the broad statutory delegation of authority to EPA, the court of appeals properly applied a "necessarily deferential" standard to EPA's decision not to hold a hearing in this case. Pet. App. 7a (internal citation omitted); 5 U.S.C. 706. Other court of appeals decisions, including some cited by petitioners, apply the same standard. See, *e.g.*, *Puerto Rico Aqueduct & Sewer Auth.* v. *EPA*, 35 F.3d 600, 604 (1st Cir.

1994) (affirming EPA hearing denial under "the busy intersection of three deferential standards of review": the APA's arbitrary or capricious standard; "the extra measure of deference with regard to factual questions involving scientific matters in [an agency's] area of expertise"; and "the respect usually accorded an agency's interpretation of a statute it is charged to execute" as well as its own regulations), cert. denied, 513 U.S. 1148 (1995); *Hynson, Westcott & Dunning, Inc.* v. *Richardson*, 461 F.2d 215, 219-220 (4th Cir. 1972) (in making hearing determinations, an agency's discretion cannot be exercised arbitrarily), aff'd as modified, 412 U.S. 609 (1973).[4]

b. In arguing that the decision below conflicts with rulings of this Court and other circuits (Pet. 20-26), petitioners rely on decisions that address evidentiary-hear-

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[4] Petitioners are wrong in arguing (Pet. 10-11, 17) that instances where EPA evaluated petitioners' evidence demonstrate that EPA failed to apply the appropriate standard to determine whether a hearing was warranted. For example, in accusing EPA of impermissibly "weighing" the evidence, petitioners quote out of context an EPA statement referencing "the totality of the evidence." Pet. 11 n.3 (quoting Pet. App. 127a). When the entire sentence from which the quote is taken is considered, however, it is apparent that EPA was properly applying the hearing standard. In full, EPA stated that it was denying the hearing request because "[t]he totality of the evidence submitted fails to demonstrate a reasonable possibility that exclusive reliance on carbofuran brain data will be protective, largely because [petitioners] have failed to proffer any evidence on several points that are critical to their argument." Pet. App. 127a-128a. EPA may properly deny a hearing on an argument that has no reasonable possibility of success due to a failure to proffer sufficient evidence, and such a denial does not amount to an improper weighing of evidence at the hearing-request phase. See 40 C.F.R. 178.32(b)(2).

ing requirements under dissimilar statutory and regulatory provisions.

Petitioners' reliance (Pet. 20-22) on this Court's decision in *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609 (1973) (*Hynson*), is misplaced. The Court in *Hynson* upheld the authority of the Food and Drug Administration (FDA) to follow a summary judgment-type procedure when determining whether a party has met its burden of establishing entitlement to an evidentiary hearing. *Id.* at 615-622. The Court concluded, however, that the FDA had erroneously denied a hearing in the case before it. *Id.* at 623.

For two principal reasons, *Hynson* does not support petitioners' theory in this case. First, the Court in *Hynson* did not explain its rationale in finding that the FDA's denial of a hearing was erroneous. The Court's entire discussion of that question came in a two-sentence statement of its bare holding. See 412 U.S. at 623 ("There is a contrariety of opinion within the Court concerning the adequacy of Hynson's submission. Since a majority are of the view that the submission was sufficient to warrant a hearing, we affirm the Court of Appeals on that phase of the case.").

Second, *Hynson* involved statutory and regulatory provisions different from those at issue here. *Hynson* involved a statutory provision that broadly provided an "opportunity for hearing," 412 U.S. at 620 (quoting 21 U.S.C. 355(e)), and a particular FDA regulation construing it, *ibid.* (citing 21 C.F.R. 130.14(b) (1972)). Accordingly, the issue in *Hynson* was whether a party requesting an FDA hearing had met *that* "statutory standard[] as particularized by [*that*] regulation[]." *Ibid.* And unlike 21 U.S.C. 346a(g)(2)(B), neither the statute nor the regulation at issue in *Hynson* gave agency offi-

cials broad discretion to "determine[ ]" whether a hearing was "necessary." Cf. p. 23, *supra*.

There is likewise no conflict between the decision below and the court of appeals decisions on which petitioners rely. The Fourth Circuit in *Hynson* held that the FDA had acted arbitrarily in denying a hearing request by a pharmaceutical company that had submitted scientific evidence showing that its drug was effective. 461 F.2d at 221-222. As noted above, however, *Hynson* involved a different regulatory scheme, and, in any event, nothing in the Fourth Circuit's fact-specific review of the record in that case conflicts with the decision below.

Petitioners' reliance on *Pactra Industries, Inc.* v. *CPSC*, 555 F.2d 677 (9th Cir. 1977), is also misplaced. That case involved a different section of the FFDCA, 21 U.S.C. 371(e), and, contrary to petitioners' characterization, (Pet. 24), the Ninth Circuit determined that Section 371(e) did *not* incorporate the summary judgment-type standard at issue here. Under the provision at issue in *Pactra*, "[h]earings are mandatory upon request," Pet. App. 106a, while here, they are to be held only "if and to the extent the Administrator determines that such a public hearing is necessary to receive factual evidence relevant to material issues of fact raised by the objections." 21 U.S.C. 346a(g)(2)(B).

4. Contrary to petitioners' contention (Pet. 31), this is not a case of "exceptional national importance." Petitioners state that "[f]or more than four decades, EPA has thwarted Congress's express hearing requirement under the FFDCA" by failing to hold hearings. *Ibid.*;

see *id.* at i, 3, 16 (repeating claim).[5] During the "four decades" prior to petitioners' request, however, EPA ruled on only *two* other such hearing requests. See 73 Fed. Reg. 42,683 (2008); 59 Fed. Reg. 33,684 (1994).[6] EPA's isolated denials of those evidentiary-hearing requests, under a statute that requires such hearings only "if and to the extent the Administrator determines" they are "necessary," 21 U.S.C. 346a(g)(2)(B), raise no issue of broad importance.

[5] In support of their hyperbolic claim that EPA has worked a "nullification of an Act of Congress," petitioners state that EPA "dismissively refers to hearings as 'time-consuming' and 'unnecessary.'" Pet. 19 (quoting Gov't C.A. Br. 5, 56); see Pet. 15 (same). The full contexts in which the quoted language appears make clear, however, that the government's argument below was consistent with routine waiver and exhaustion principles. See Gov't C.A. Br. 5 ("EPA reasonably interprets the statute's two-stage administrative process in a way that ensures *both* stages of the process will be meaningful. Its interpretation reflects Congress' intent to limit the use of a time-consuming evidentiary hearing to those instances in which a genuine material factual issue exists as to EPA's factual determinations in a final revocation rule."); *id.* at 56 ("Without a waiver doctrine that limits the second stage to a review of the matters determined in the first stage, not only would the rulemaking phase be rendered superfluous, but parties would be encouraged to engage in gamesmanship in the hope of delaying ultimate EPA resolution of the matter and EPA could be forced to devote limited resources to hearings which may have been unnecessary.").

[6] Since EPA's denial of the evidentiary-hearing request regarding carbofuran, the agency has denied one additional hearing request. See 75 Fed. Reg. 55,997 (2010). Petitioners' remaining citations to EPA decisions (Pet. 16 n.5) do not involve evidentiary-hearing requests under the FFDCA.

## CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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APRIL 2011

187

(7)

No. 10-1031

# In the Supreme Court of the United States

NATIONAL CORN GROWERS ASSOCIATION, ET AL.,
*Petitioners,*

v.

U.S. ENVIRONMENTAL PROTECTION AGENCY, ET AL.,
*Respondents.*

ON PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

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## TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES ..... ii

INTRODUCTION ..... 1

I. THE QUESTION PRESENTED IS UNDENIABLY IMPORTANT ..... 3

II. DESPITE EPA'S ATTEMPT TO RECAST IT, THE DECISION BELOW IS SHARPLY OUT OF STEP WITH EXISTING PRECEDENT ..... 5

III. EPA'S NOVEL WAIVER REGIME ONLY HEIGHTENS THE NEED FOR REVIEW ..... 9

CONCLUSION ..... 12

ADDENDUM

Compilation of Expert Materials Submitted to EPA in Administrative Proceedings and List of Experts That Presented Materials

Expert Materials Relating to Ground Water and Surface Water Exposures ..... 1a

Expert Materials Relating to Human Health and Dietary Exposure ..... 5a

Experts Who Conducted Studies, Submitted Expert Reports, or Testified in Support of Carbofuran ..... 8a

# TABLE OF AUTHORITIES

Page(s)

## CASES

*Hynson, Westcott & Dunning, Inc. v. Richardson*,
461 F.2d 215 (4th Cir. 1972) ..... 8

*Massachusetts v. EPA*,
549 U.S. 497 (2007) ..... 8

*Pactra Industries, Inc. v. CPSC*,
555 F.2d 677 (9th Cir. 1977) ..... 8, 9

*Weinberger v. Hynson, Westcott & Dunning, Inc.*,
412 U.S. 609 (1973) ..... 7

*Winter v. NRDC*,
129 S. Ct. 365 (2008) ..... 1

*Woodford v. Ngo*,
548 U.S. 81 (2006) ..... 10

## STATUTES AND REGULATIONS

Food Quality Protection Act of 1996, Pub. L. No. 104-170, § 405, 110 Stat. 1489 ..... 8

40 C.F.R. § 178.32 ..... 6

40 C.F.R. § 178.32(b) ..... 8

## TABLE OF AUTHORITIES—Continued

Page(s)

### FEDERAL REGISTER

40 Fed. Reg. 22,950 (May 27, 1975) ..... 7

55 Fed. Reg. 50,282 (Dec. 5, 1990) ..... 8

74 Fed. Reg. 59,608 (Nov. 18, 2009)..... 6, 10

### OTHER AUTHORITY

H.R. Rep. No. 104-669, pt. 2 (1996) ..... 8

## INTRODUCTION

Because EPA tries to recast the decision below, we begin by restating the holding of the court of appeals on when a hearing is required under the statute and regulations at issue: "[T]he FFDCA and the EPA's regulations establish a 'summary-judgment type' standard for determining whether to hold a hearing: The EPA must hold a hearing if it determines an objection raises a material issue of fact." Pet. App. 6a. Critically, however, the court of appeals also held that a "dispute between experts"—which, as the court correctly stated, "accurate[ly]" describes the dispute in *this* case—is "fatal" to finding a disputed issue of material fact. *Id.* at 13a. And the court further held that judicial review of EPA's determination that an issue of disputed material issue does not exist is essentially hands off. *Id.* at 7a. That ruling not only directly conflicts with the decisions of this Court and other circuits, *see* Pet. 14-26, it effectively guts the statutory hearing right at issue in this case.

This case is a poster child for why the FFDCA's hearing requirement is necessary. It is undisputed both that (1) the pesticide that EPA essentially banned in the proceedings below—carbofuran—was used safely for four decades without a *single* incident of dietary or drinking water exposure causing any observable symptoms—let alone serious injury, and (2) that perfect safety record was accomplished even while the amount of carbofuran used was *50 times* greater than today, on as many as 35 domestic crops grown widely throughout the country. *See* Pet. 7-8; *cf. Winter v. NRDC*, 129 S. Ct. 365 (2008) (emphasizing absence of any documented case of harm to marine mammals despite 40-year history of naval exercises at issue).

Yet at significant economic and practical expense to American businesses, farmers, and consumers, EPA has now banned the use of that product without even affording the manufacturer a hearing on safety—based on the premise that it is so obvious that carbofuran is *unsafe* at the much, much *lower* levels that are used today that there is not even a disputed issue of material fact warranting a hearing.

As a common sense matter, that conclusion does not pass the straight face test. And as a legal matter, the conclusion cannot be squared with the standard that EPA itself "agree[d]" governs this case (Pet. App. 6a)—and that follows from the decisions of this Court and those of other circuits. Pet. 20-25. Moreover, EPA's implausible conclusion that no material issue of fact exists not only fails to account for the mountain of expert evidence petitioners presented showing that carbofuran is safe at the levels at issue, *see* Add. 1a-8a, but is based on completely unrealistic assumptions. For example, EPA assumed that *100%* of every relevant crop—everywhere—would be treated by carbofuran simply because that was "legally permissible," even though county-level sales never exceeded *4.25%* anywhere in the country. Pet. 9.[1] EPA also erected an extraordinary waiver regime to bar a hearing. EPA's waiver rules only heighten the need for review here. But even excluding the evidence that EPA erroneously says was waived, there was more than ample evidence to require a hearing.

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[1] EPA derides the 4.25% figure as "*sales* data." Opp. 14 (emphasis in original). But sales data is a common-sense way of gauging use. And in any event, quibbling at the margins of petitioners' 4.25% figure in no way accounts for EPA's wildly inaccurate *100%* figure.

In the 40 years of the FFDCA, EPA has *never* found a single disagreement with its positions that it believed sufficient to give rise to a material issue of fact requiring a hearing. Not one. And EPA already has seized on the decision below to deny a subsequent hearing request—by an environmental group challenging the safety of a product. *Id.* at 13. Because that decision not only eviscerates a critical statutory hearing right, but does so in a manner that directly conflicts with the decisions of this Court and other circuits, this Court's review is warranted.

## I. THE QUESTION PRESENTED IS UNDENIABLY IMPORTANT

EPA cavalierly states that the decision below raises "no issue of broad importance." Opp. 27. Associations representing companies across the country engaged in agricultural crop protection, chemistry, manufacturing, pharmaceuticals and biotechnology, and food and beverages, as well as millions of American farmers and nonprofit public interest organizations dedicated to studying the impact of government on Americans, all disagree. *See* Br. of Amici American Chemistry Council *et al.* (ACC Br.); Br. of Amici CropLife America *et al.* (CropLife Br.); Br. of Amici Pacific Legal Foundation *et al.* (PLF Br.). As they have explained, those organizations are all directly affected by the District of Columbia Circuit's decision in this case. And they all agree that "[t]his case raises fundamentally important issues of administrative law warranting this Court's review." CropLife Br. 2; *see* ACC Br. 4 ("question presented is of exceptional importance"); PLF Br. 2 (case of "vital concern").

These amici recognize that the decision below is by no means "limited to carbofuran or pesticides alone,"

PLF Br. 7, but rather will "likely have a significant negative impact on American industrial concerns." ACC Br. 11. Indeed, amici have explained that "[i]t does not overstate the case to say that the decision below gives the EPA *carte blanche* to determine the fate of literally thousands of products in the market," including prescription drugs, medical devices, agriculture, cosmetics, food products, and other consumer goods. PLF Br. 7; *see* ACC Br. 12. As amici have further explained, Congress has adopted analogous hearing requirements "in several statutes empowering agencies to ban products, and the vast majority of agency decisions are subject to review in the [District of Columbia] Circuit." CropLife Br. 4; *see* ACC Br. 15-17 (discussing "[n]umerous other governmental agencies [that] employ" analogous summary judgment-type procedures). Moreover, amici have explained that statutory hearing rights like the one at issue here "protect[] American industry and consumers from misinformed, ill-conceived regulation of a staggering array of products." ACC Br. 12.

Amici also recognize that the decision directly conflicts with the decisions of this Court and other circuits involving analogous regulatory hearing requirements. CropLife Br. 14-15; PLF Br. 13-14; *see also* ACC Br. 8. EPA unpersuasively attempts to distinguish those cases on the basis of distinctions that it did not draw below. *See* Opp. 24-27; pp. 7-9, *infra*. But the District of Columbia Circuit's *decision* is by no means limited by the *post hoc* distinctions EPA attempts to draw. Instead, the court's ruling is grounded on broadly applicable principles governing what constitutes a "material issue of fact" and what standard of judicial review applies to an agency's

determination that one does not exist. These principles apply directly to numerous other administrative summary judgment-type schemes. Pet. App. 6a-7a. That is why such a broad swath of American industry, farmers, and others are so concerned about the decision below. EPA has no persuasive response.

## II. DESPITE EPA'S ATTEMPT TO RECAST IT, THE DECISION BELOW IS SHARPLY OUT OF STEP WITH EXISTING PRECEDENT

EPA offers little defense of the District of Columbia Circuit's remarkable conclusion that a "dispute between experts," Pet. App. 13a, on the outcome-determinative issue of water safety did not entitle petitioners to a hearing under EPA regulations establishing that it "*must* hold a hearing if it determines an objection raises a material issue of fact," *Id.* at 6a (emphasis added). Instead, the agency's main contention is that this Court should simply ignore that far-reaching ruling. That argument is unavailing.

The District of Columbia Circuit held that this case is "accurate[ly]" described as a "dispute between experts." *Id.* at 13a. And that conclusion is unassailable. Petitioners submitted "extensive Comments in response to the proposed revocation," *id.* at 5a, along with 44 expert reports, studies, and analyses on human health/dietary and water risk issues alone. *See* Add. 1a-8a. Petitioners' objections and request for hearing similarly identified with particularity the numerous evidentiary submissions supporting their position and the asserted flaws with EPA's conclusions. *See* Pet. App. 440a-55a. EPA's refusal to recognize "any 'expert' opinion that could have created a legitimate factual dispute in this case," Opp. 14 (citation omitted); *see id.* at 15, simply

underscores that EPA categorically rejects *any* contrary expert opinion.

The District of Columbia Circuit's holding that this prototypical expert dispute over water safety did not require a hearing is part and parcel of the judgment under review. Without any "in any event" or other qualifying language, the court expressly acknowledged the "dispute between experts" over groundwater safety; held that it was "fatal" to petitioners' case; and immediately thereafter held that "petitioners have failed to show a hearing was warranted on either of the first two issues of fact they raised," explaining that "we will not overturn an agency's finding there is no material issue of fact based upon '[m]ere differences in the weight or credence given to particular studies.'" Pet. App. 13a (citation omitted). At a bare minimum, that holding warrants further review.

If "mere differences" in expert testimony or reports concerning "outcome-determinative" facts like safety are not sufficient to warrant a hearing, nothing is. EPA has made clear that *non-expert* testimony and objections shall be treated as "mere allegations and general denials and contentions, which EPA regulations expressly provide to be insufficient to justify a hearing." 74 Fed. Reg. 59,608, 59,622 (Nov. 18, 2009); *id.* at 59,622-23 (citing 40 C.F.R. § 178.32). And the decision below gives the agency *carte blanche* to decide what *expert* testimony—if any in the agency's view—is sufficient to warrant a hearing. So in the wake of the District of Columbia Circuit's decision in this case, a party like petitioners here opposing EPA's decision to ban a product used safely for decades can *never* obtain a hearing except by EPA grace—

something EPA has not seen fit to exercise in the four decades it has administered the hearing right at issue.

That result is directly at odds with the precedents of this Court and other courts. Pet. 20-26. As this Court made clear in *Weinberger v. Hynson, Wescott & Dunning, Inc.*, summary judgment is appropriate *only* where "the applicant has not tendered *any* evidence which *on its face* meets the statutory standards as particularized by the regulations." 412 U.S. 609, 620 (1973). There can be no serious dispute that petitioners' evidence satisfies *that* standard. Pet. 20-21. And in *Weinberger* this Court upheld the Fourth Circuit's conclusion that a hearing was required to resolve a "battle of the experts" under a directly analogous hearing provision. *Id.* at 23-24.

EPA never seriously attempts to account for the direct conflict with *Weinberger*. First, EPA weakly suggests that this Court "did not explain its rationale" in finding that a hearing was required in *Weinberger*. Opp. 25. But as discussed, the decision below directly conflicts with several different facets of this Court's explicit holdings in *Weinberger*, not to mention the Fourth Circuit decision *upheld* in *Weinberger*. Pet. 20-24. Next, EPA says that *Weinberger* involved different "statutory and regulatory provisions." Opp. 25. But the District of Columbia Circuit's decision in this case did not rely in any way on the purported statutory distinctions that EPA now attempts to draw. More to the point, EPA itself has explicitly acknowledged that its "hearing request requirements are based *heavily* on FDA [hearing] regulations," Pet. App. 82a (emphasis added), which FDA has made clear "accurately reflect the legal standards enunciated by" *Weinberger*, 40 Fed. Reg. 22,950, 22,968 (May 27, 1975).

In any event, EPA's statutory argument (Opp. 22-23)—based on Section 408(g)'s use of "determine[]" and "necessary"—fails on two different levels. First, the language on which EPA now relies was added in 1996 and thus *post-dates* EPA's own hearing regulation. *Compare* Food Quality Protection Act of 1996, Pub. L. No. 104-170, § 405, 110 Stat. 1489, 1525 *with* 55 Fed. Reg. 50,282, 50,292 (Dec. 5, 1990). EPA's regulations explicitly provide that "[a] request for an evidentiary hearing *will be granted*" if "'[t]here is a genuine and substantial issue of fact for resolution.'" Pet. App. 3a (emphasis added) (quoting 40 C.F.R. § 178.32(b)). The 1996 amendments by no means intended to alter that rule. *See* H.R. Rep. No. 104-669, pt. 2, at 49 (1996) (Congress "expects EPA ... to grant hearings to responsible parties *on all sides*") (emphasis added). And second, EPA's argument simply proves too much and only further underscores that EPA seeks essentially unreviewable discretion to make hearing determinations. *Cf. Massachusetts v. EPA*, 549 U.S. 497, 533 (2007) (provision of "judgment" to EPA is not a limitless grant of authority, but rather "a direction to exercise discretion within defined statutory limits").

The District of Columbia Circuit's holding concerning when a material issue of fact exists also directly conflicts with the decisions of the Fourth and Ninth Circuits recognizing that administrative hearings are required under analogous summary judgment-type procedures when a party demonstrates a "genuine and substantial issue of fact." *Hynson, Westcott & Dunning, Inc. v. Richardson*, 461 F.2d 215, 219 (4th Cir. 1972); *see also Pactra Indus., Inc. v. CPSC*, 555 F.2d 677, 684 (9th Cir. 1977) (Kennedy, J.). Indeed, in *Pactra*, the court held that a hearing may

not be denied "merely because *the agency* has concluded that the scientific evidence is adequate to support its order." 555 F.2d at 684 (emphasis added). The basic conflict concerns *when* an expert dispute creates a material issue of fact. The distinctions that EPA now attempts to draw among the underlying provisions are non-responsive because EPA has already "agree[d]" that it "*must* hold a hearing" under the FFDCA when such a disputed issue of material fact exists. Pet. App. 6a (emphasis added).

## III. EPA'S NOVEL WAIVER REGIME ONLY HEIGHTENS THE NEED FOR REVIEW

Rather than addressing the District of Columbia Circuit's decision on its own terms or genuinely accounting for the multiple conflicts presented, EPA suggests that this case is "a poor vehicle" for addressing the important question presented because of what EPA calls petitioners' "serial waivers." Opp. 14. But EPA has it backwards. EPA's "Catch 22" waiver rules—which were upheld by the decision below—only further trample on the FFDCA's hearing requirement and thus increase the need for review.

Although the government is invariably fond of invoking waiver principles, the waiver rules at issue here are by no means custom fare. As explained, EPA's waiver rules not only conflict with the text of the relevant statutory and regulatory provisions, they effectively ensure that virtually *any* argument may be rejected on the ground that they were raised *too early* or *too late*. Pet. 27-29. For example, because EPA's rules treat as waived "'any issue not originally raised in comments,'" Opp. 17 (citation omitted), petitioners submitted substantial comments and expert evidence refuting EPA's factual determinations. At the

objections and hearing request stages, however, EPA refused to consider those comments and supporting evidence on the ground that they were "recycled" from the earlier phase. 74 Fed. Reg. at 59,609.

The court of appeals nevertheless broadly affirmed this "Tails-I-Win, Heads-You-Lose" waiver regime. Under the court's decision, when a petitioners' submissions fail to convince the agency to alter its own proposed regulation or analysis in its final regulation, a petitioner is powerless to obtain a hearing, even when its comments or objections raised a material issue of fact. And that is true even when EPA's analysis on outcome-determinative issues *changes* from the the *Proposed Rule* to the *Final Rule*. Pet. 28-29. The upshot is that EPA's waiver rules essentially leaves the agency free to ignore whatever submissions it deems inconvenient. And under the decision below, the courts must disregard evidence EPA deems waived in determining whether a hearing is required, even when it is undisputed that the evidence was before EPA.[2]

Administrative exhaustion requirements typically ensure the presentation of an issue to allow for full agency consideration and to "'produce a useful record for subsequent judicial consideration.'" *Woodford v. Ngo*, 548 U.S. 81, 89 (2006) (citation omitted). In contrast, the EPA's waiver regime—upheld by the decision below—enables the agency to *avoid* the development of a record and to *preclude* judicial review

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[2] EPA's rehearing analogy (Opp. 18) is fundamentally flawed. It is not unusual for a petition for rehearing to renew arguments made in the principal briefs. Moreover, making an argument on rehearing by no means prevents a party from making it in the next stage of review. In EPA's Orwellian waiver parlance, however, such arguments would be "recycled," and thus waived.

altogether. Moreover, EPA's waiver rules do not encourage the presentation of the right issues to the right tribunal at the right time; they create a no-win gauntlet with no basis in the statute or regulations, which a petitioner's genuine hearing request cannot survive unless EPA so chooses. Not surprisingly, the District of Columbia Circuit's decision embracing that extraordinary regime conflicts with the decisions of this Court and other circuits. Pet. 29-31.

This case aptly illustrates how EPA's waiver rules operate systematically to destroy genuine hearing requests. Petitioners conscientiously presented expert report after expert report at every stage of the proceedings to establish what ought to follow as a matter of common sense in light of the lack of evidence that carbofuran posed any harm during the 40 years it was used at much higher levels: there is, at the very least, a material issue of disputed fact concerning whether carbofuran is safe, especially at the relatively low levels at issue here. Yet EPA managed to shred that hearing request through the application of its whip-saw waiver rules, and the District of Columbia Circuit's decision broadly affirms that result. That far-reaching decision warrants this Court's review.

## CONCLUSION

For the foregoing reasons, and those in the petition, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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# ADDENDUM

## TABLE OF CONTENTS

Compilation of Expert Materials Submitted to EPA in Administrative Proceedings and List of Experts That Presented Materials

Expert Materials Relating to Ground Water and Surface Water Exposures ..... 1a

Expert Materials Relating to Human Health and Dietary Exposure ..... 5a

Experts Who Conducted Studies, Submitted Expert Reports, or Testified in Support of Carbofuran ..... 8a

# EXPERT MATERIALS RELATING TO GROUND WATER AND SURFACE WATER EXPOSURES

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11. Williams, W.M., Engel B., Fawcett, R., Dasgupta S., and C.G. Hoogeweg, *An In-Depth Investigation to Estimate Surface Water Concentrations of Carbofuran within Indiana Community Water Supplies.* PC-0378 (Aug. 29, 2007).

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18. Lamb, J., Sielken, R., and R. Morris, *Comments to the FIFRA Scientific Advisory Panel: The Dietary Risk Assessment for Carbofuran* (Jan. 22, 2008).

19. * Barraj, L. and Polakoff, B., *Carbofuran Dietary Risk Assessment* (June 30, 2009).

20. * Hoogeweg, G. and Williams, W.M., *Groundwater pH in selected states.* Memo to Dylan Fuge, Latham & Watkins (June 30, 2009).

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* An asterisk denotes material that was submitted to EPA during the administrative proceedings below but which EPA has claimed was waived under the waiver rules at issue. As explained in the certiorari petition and this reply brief, those rules should not be given effect. But in any event, as these tables illustrate, the vast majority of expert materials presented by petitioners are not subject to waiver claims at all

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Supreme Court of the United States

NATIONAL CORN GROWERS ASSOCIATION, ET. AL.,
*Petitioners,*

v.

U.S. ENVIRONMENTAL PROTECTION AGENCY, ET. AL.,
*Respondent.*

On Petition For A Writ Of Certiorari
To The United States Court of Appeals
For The District Of Columbia Circuit

# BRIEF OF AMERICAN CHEMISTRY COUNCIL, THE NATIONAL ASSOCIATION OF MANUFACTURERS, THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, AMERICAN BEVERAGE ASSOCIATION, AND GROCERY MANUFACTURERS ASSOCIATION, AS AMICI CURIAE IN SUPPORT OF PETITIONERS

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## QUESTION PRESENTED

For nearly forty years, the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. § 346a(g)(2)(B), has required the Environmental Protection Agency (EPA) to hold a public evidentiary hearing before taking certain major agency actions, when a party objects to the proposed action and satisfies what the agency itself has described as "summary judgment-type procedures" that, among other things, require a hearing to resolve "disputed material factual issues." 74 Fed. Reg. 59,608, 59,623 (Nov. 18, 2009); see 40 C.F.R. § 178.32(b). During that time, EPA has never held such a hearing.

In this case, EPA refused to hold such a hearing before revoking the tolerances for—and thus effectively banning—a pesticide that has been used safely for decades, even though petitioners filed timely objections supported by ample expert data and other evidence calling into serious question the agency's findings on several material issues of fact. The District of Columbia Circuit upheld EPA's decision, holding that review of such a denial is highly deferential, that—paradoxically—the existence of an expert dispute over a critical factual issue was "fatal" to petitioners' request for a hearing, and that the agency properly refused to consider various objections based on "Catch-22" timing considerations.

If a hearing is not required under the FFDCA in this type of case, then as a practical matter the Act's hearing requirement is illusory. The question presented is whether the District of Columbia Circuit—in conflict with the decisions of this Court and other circuits, as well as with the agency's own regula-

tions—has properly construed the FFDCA's hearing requirement and related rules.

## TABLE OF CONTENTS

Page

QUESTION PRESENTED ..... i

INTEREST OF THE AMICI ..... 1

SUMMARY OF ARGUMENT ..... 4

ARGUMENT ..... 4

I. ADMINISTRATIVE AGENCY HEARINGS BEFORE A NEUTRAL FACTFINDER ARE ESSENTIAL TO DUE PROCESS ..... 4

II. THE COURT OF APPEALS' OPINION UNDERMINES DUE PROCESS BY EVISERATING ANY MEANINGFUL RIGHT TO A HEARING UNDER 21 U.S.C. § 346A ..... 7

III. THE COURT OF APPEALS' OPINION LIKELY WILL NEGATIVELY IMPACT INDUSTRY IN THE UNITED STATES ..... 11

A. American Industry Relies On The Right To A Hearing As A Fundamental Component Of The Administrative State. ..... 12

B. This Court's Review Is Warranted Because Numerous Governmental Agencies Employ A "Summary Judgment-type" Procedure When Determining Whether To Grant A Hearing ..... 15

CONCLUSION ..... 18

## TABLE OF AUTHORITIES

Page(s)

CASES

*Anderson Nat'l Bank v. Luckett*,
321 U.S. 233 (1944) ..... 5

*Brock v. Roadway Exp., Inc.*,
481 U.S. 252 (1987) ..... 4

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470 U.S. 532 (1985) ..... 5

*Edison Pharm. Co. v. FDA*,
513 F.2d 1063 (D.C. Cir. 1975) ..... 9

*FCC v. Pottsville Broadcasting Co.*,
309 U.S. 134 (1940) ..... 6

*Giant Food, Inc. v. FTC*,
322 F.2d 977 (D.C. Cir. 1963) ..... 6, 10

*Goldberg v. Kelly*,
397 U.S. 254 (1970) ..... 4

*Hynson, Westcott & Dunning, Inc. v. Richardson*,
461 F.2d 215 (4th Cir. 1972) ..... 13

*Int'l Shoe Co. v. Washington*,
326 U.S. 310 (1945) ..... 17

## TABLE OF AUTHORITIES
(continued)

Page(s)

*Mathews v. Eldridge*,
424 U.S. 319 (1976) ..... 4-5

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613 F.3d 266 (D.C. Cir. 2010) ..... 3, 4

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412 U.S. 609 (1973) ..... 4, 8

STATUTES

5 U.S.C. § 556 ..... 5

7 U.S.C. § 136d ..... 14

21 U.S.C. § 234 ..... 13

21 U.S.C. § 321 ..... 12

21 U.S.C. § 335a ..... 12

21 U.S.C. § 335c ..... 12

21 U.S.C. § 344 ..... 13

21 U.S.C. § 346a ..... 4, 7, 11

## TABLE OF AUTHORITIES
(continued)

Page(s)

21 U.S.C. § 348 ..... 14

21 U.S.C. § 355 ..... 13

21 U.S.C. § 360e ..... 14

**Legislative History**

S. Rep. No. 752 (1945) ..... 5

H. R. Rep. No. 1980 (1946) ..... 6

## INTEREST OF THE AMICI[1]

**American Chemistry Council ("ACC")**, is a trade organization that represents the leading companies engaged in the business and science of chemistry to make innovative products and services that make people's lives better, healthier and safer. Its members include organizations and companies doing business in the United States including companies interested in preserving procedural safeguards in chemical registration and cancellation actions. *See* ACC's website, http://www.americanchemistry.com.

**The National Association of Manufacturers ("the NAM")** is the nation's largest industrial trade association, representing small and large manufacturers in every industrial sector and in all 50 states. The NAM's mission is to enhance the competitiveness of manufacturers by shaping a legislative and regulatory environment conducive to U.S. economic growth and to increase understanding among policymakers, the media and the general public about the vital role of manufacturing to America's economic future and living standards.

**The Pharmaceutical Research and Manufacturers of America ("PhRMA")** is a non-profit association that represents the country's leading research-based pharmaceutical and biotechnology

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[1] Pursuant to Supreme Court Rule 37.6, counsel for the amici curiae represent that they authored this brief in its entirety and that none of the parties or their counsel, nor any other person or entity other than the amici, their members, or their counsel, made a monetary contribution intended to fund the preparation or submission of this brief. All parties have consented to the filing of this brief, and letters reflecting their consent have been filed with the Clerk.
Counsel of record for all parties received notice at least 10 days prior to the due date of *amici curiae*'s intention to file this brief.

companies.[2] PhRMA advocates in support of public policies that encourage the discovery of life-saving and life-enhancing new medicines for patients by pharmaceutical and biotechnology research companies. In support of that mission, PhRMA's members invested over $300 billion in the last decade to develop new medicines. *See* PhRMA, Pharmaceutical Industry Profile 2010, at 44 (2010). In 2010 alone, PhRMA members invested approximately $49.4 billion (of an industry total of approximately $67.4 billion) in discovering and developing new medicines.[3] PhRMA closely monitors legal issues that impact the pharmaceutical industry and has regularly participated as amicus curiae in cases before the Court. *See, e.g., Graham Cnty. Soil & Water Conservation Dist.*, 129 S. Ct. 2824 (2010); *Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems (Stanford v. Roche)* (No. 09-1159) (merits amicus brief submitted Feb. 1, 2011); *Astra USA, Inc. v. County of Santa Clara* (No. 09-1273) (merits amicus brief submitted Nov. 19, 2010); *Matrixx Initiatives v. Siracusano* (No. 09-1156) (merits amicus brief submitted Aug. 27, 2010).

**American Beverage Association** represents the broad spectrum of companies that manufacture and distribute non-alcoholic beverages in the United States. It has more than 1,700 member companies that employ more than 208,000 people across the

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[2] A list of PhRMA's members can be found at http://www.phrma.org/about/member-companies.

[3] Burrill & Company, analysis for PhRMA, 2011 (includes PhRMA research associates and nonmembers); Pharmaceutical Research and Manufacturers of America, PhRMA Annual Member Survey (Washington, DC: PhRMA, 2010–2011).

country. These companies market hundreds of products including regular and diet soft drinks, bottled water and water beverages, 100 percent juice and juice drinks, sports drinks, energy drinks and ready-to-drink teas.

**The Grocery Manufacturers Association ("GMA")** is the largest association of food, beverage, and consumer product companies in the world. Its members employ more than 2.5 million workers in all fifty States, with United States sales totaling over $460 billion annually. GMA leads efforts to increase growth and productivity in the food and beverage industry, and also works to promote the safety and security of the Nation's food supply. The organization applies legal, scientific, and political expertise from its member companies to vital public policy issues affecting the industry, and speaks for food and consumer product manufacturers at the State, federal, and international levels on legislative and regulatory issues.

Together, the amici curiae represent a broad spectrum of American industry. They are concerned that the United States Court of Appeals for the District of Columbia's opinion in *National Corn Growers Association v. EPA*, 613 F.3d 266 (D.C. Cir. 2010), threatens the right to a hearing to determine disputed issues of material fact, which is frequently required by statute and is a fundamental component of due process in the administrative state.

## SUMMARY OF ARGUMENT

The United States Court of Appeals for the District of Columbia's opinion in *National Corn Growers Association v. EPA*, 613 F.3d 266 (D.C. Cir. 2010), eviscerates the right to a hearing under 21 U.S.C. § 346a(g)(2)(B). *See* Pet. App. 1a-15a. The EPA's own implementing regulations direct the agency to evaluate whether to grant a hearing with a "summary judgment-type" procedure. Pet App. 432a-433a; *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 622 (1973). Yet, the Court of Appeals' opinion allows the EPA to deny a hearing, even when faced with disputed material facts. Furthermore, the Court of Appeals' opinion approved of the EPA's "Catch 22" timing rules, allowing the EPA to accept or reject evidence at will. Because the right to a hearing is fundamental to a well-informed, equitable administrative process, the question presented is of exceptional importance. Accordingly, the amici curiae respectfully submit that this Court's review is warranted, and the Court of Appeals' judgment should be reversed.

## ARGUMENT

### I. ADMINISTRATIVE AGENCY HEARINGS BEFORE A NEUTRAL FACTFINDER ARE ESSENTIAL TO DUE PROCESS.

It is beyond contest that "[t]he fundamental requisite of due process of law is the opportunity to be heard." *Goldberg v. Kelly*, 397 U.S. 254, 267 (1970) (quoting *Grannis v. Ordean*, 234 U.S. 385, 394 (1914)). *See also Brock v. Roadway Exp., Inc.*, 481 U.S. 252, 261 (1987) (stating that "the fundamental requirement of due process is the opportunity to be heard") (citation omitted); *Mathews v. Eldridge*, 424

U.S. 319, 333 (1976) ("The fundamental requirement of due process is the opportunity to be heard at a meaningful time and in a meaningful manner.") (citation omitted); *Anderson Nat'l Bank v. Luckett*, 321 U.S. 233, 246 (1944) (stating that "[t]he fundamental requirement of due process is an opportunity to be heard").

Accordingly, evidentiary hearings before neutral factfinders are the heart of the due process guarantee. A hearing is the key forum for "balancing . . . the competing interests at stake" in a given dispute and resolving disputed issues of material fact. *Cleveland Bd. of Educ. v. Loudermill*, 470 U.S. 532, 542 (1985). Hearings permit a thorough vetting of contested facts and theories through cross-examination. *See Perry v. Leeke*, 488 U.S. 272, 283 n.7 (1989) ("The age-old tool for ferreting out truth in the trial process is the right to cross-examination. For two centuries past, the policy of the Anglo-American system of evidence has been to regard the necessity of testing by cross-examination as a vital feature of the law.") (quoting 5 WIGMORE EVIDENCE § 1367 (Chadbourn rev. 1974).

Like judicial hearings, administrative agency hearings are key forums for uncovering truth and ensuring a just result. In an administrative agency hearing, contested ideas are challenged, weighed, and measured. As the Administrative Procedure Act provides, "[a] party is entitled to present his case or defense by oral or documentary evidence, to submit rebuttal evidence, and to conduct such cross-examination as may be required for a full and true disclosure of the facts." 5 U.S.C. § 556(d). *See also* S. Rep. No. 752, 79th Cong., 1st Sess., at 23 (1945) (stating that "[t]o the extent that cross-examination

is necessary to bring out the truth, the party should have it"); H. R. Rep. No. 1980, 79th Cong., 2d Sess., at 37 (1946) (stating that "[t]o the extent that cross-examination is necessary to bring out the truth, the party must have it").

Due process necessitates that, where appropriate, administrative agencies hold hearings to review evidence and hear argument in order to resolve disputed issues of material fact. Without the procedural safeguards afforded by a hearing before a neutral factfinder, administrative agencies would be free to act — and indeed, may be unable to avoid acting — in a short-sighted and under-informed manner. To guard against such an inevitability, Congress has provided for administrative agencies to hold public hearings to address disputed issues of material fact.

As this Court has stated, "the laws under which [administrative] agencies operate prescribe the fundamentals of fair play. They require that interested parties be afforded an opportunity for hearing and that judgment must express a reasoned conclusion." *FCC v. Pottsville Broad. Co.*, 309 U.S. 134, 143-44 (1940). Because administrative agencies are, "at once, the accuser, the prosecutor, the judge and the jury, [administrative agencies] must remain alert to observe accepted standards of fairness." *Giant Food, Inc. v. FTC*, 322 F.2d 977, 984 (D.C. Cir. 1963) (citation omitted). To that end, "reviewing courts must . . . be alert to ascertain that the true substance of a fair hearing is not denied to a party." *Id.*

## II. THE COURT OF APPEALS' OPINION UNDERMINES DUE PROCESS BY EVISERATING ANY MEANINGFUL RIGHT TO A HEARING UNDER 21 U.S.C. § 346A.

In the Federal Food, Drug and Cosmetics Act ("FFDCA"), Congress provided that the EPA would hold public hearings to resolve factual disputes relevant to proposed agency action. Pet App. 405a. The FFDCA requires the EPA to hold a hearing "if and to the extent the Administrator determines that such a public hearing is necessary to receive factual evidence relevant to material issues of fact raised by the objections" to a Final Regulation published by the agency. *Id.*

The EPA's own implementing regulations provide as follows:

> A request for *an evidentiary hearing will be granted* if the Administrator determines the material submitted shows the following:
>
> (1) There is a *genuine and substantial issue of fact* for resolution at a hearing. An evidentiary hearing will not be granted on issues of policy or law.
>
> (2) There is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor . . . An evidentiary hearing will not be granted . . . if the Administrator concludes that the data and information submitted, even if accurate, would be insufficient to justify the factual determination urged.

> (3) Resolution of the factual issue(s) in the manner sought . . . would be adequate to justify the action requested. An evidentiary hearing will not be granted on factual issues that are not determinative with respect to the action requested.

Pet. App. 432a-433a (emphasis added). Thus, the EPA must hold a hearing when an objection raises a material issue of fact.

The EPA has recognized that the determination whether it must hold a hearing is akin to a "summary judgment-type" procedure. Pet. App. 82a-83a. As the EPA has stated, "Congress confirmed EPA's authority to use summary judgment-type procedures with hearing requests when it amended FFDCA section 408 in 1996." Pet. App. 83a. *See also Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 622 (1973) (approving the FDA's use of a summary judgment procedure to determine when to hold a hearing); Pet. App. 6a ("The parties agree the FFDCA and the EPA's regulations establish a 'summary-judgment type' standard for determining whether to hold a hearing: The EPA must hold a hearing if it determines an objection raises a material issue of fact.").

Given that the EPA has recognized that a "summary judgment-type" procedure is appropriate for determining whether to hold a hearing, one might assume that the EPA consistently holds hearings whenever an objection raises a material issue of fact. But, in actuality, the EPA has not held a hearing in forty years. It is inconceivable that no objection has raised a single issue of material fact warranting a

hearing in that extended period. While the EPA has recognized that a "summary judgment-type" procedure is appropriate, the EPA has failed to employ such a procedure. The inescapable conclusion is that the EPA is steadfastly refusing to follow both Congress' direction and its own implementing regulations.

As the United States Court of Appeals for the District of Columbia previously stated with respect to the FDA's consistent failure to grant evidentiary hearings: "In our eyes, this failure to grant a hearing to any applicant casts doubt upon the good faith we would ordinarily impute without question to a decision" of the agency. *Edison Pharm. Co. v. FDA*, 513 F.2d 1063, 1072 (D.C. Cir. 1975). In *Edison*, the court was duly concerned that the FDA had not granted a request for a hearing on a new drug application in approximately *three years*. *Id.* The EPA's failure to grant an evidentiary hearing in *forty years* should warrant far greater heightened skepticism here. Yet, in contrast with its prior opinion, in this case, the Court of Appeals has greatly enabled EPA's lawless refusal to hold required evidentiary hearings.

If there will ever be a case raising material factual disputes that warrant a hearing, this is it. The law is clear that when there is a disputed issue of material fact, the EPA is required to hold a hearing before revoking a tolerance for a pesticide. *See* Pet. App. 405a. In this case, a hearing was explicitly required by statute. *Id.* Petitioners presented the EPA with numerous consequential disputed issues of fact regarding the tolerance revocation at issue. For example, the EPA decided to revoke the tolerance for the pesticide on the basis of an entirely unrealistic

assumption — that the pesticide would be applied to 100% of the crops in any given watershed. Pet App. 7a. In stark contrast, as the petitioners sought to demonstrate, the pesticide would only be applied to 4.25% of crops in any watershed. *Id.* Additionally, petitioners submitted comments demonstrating that, in contrast to the EPA's conclusion, the pesticide exposure levels in surface and ground waters were safe. *Id.* at 11a-12a. But the petitioners were denied a hearing. The EPA's actions fail to demonstrate even rudimentary fairness. *Giant Food, Inc.*, 322 F.2d at 984.

Yet, rather than provide any meaningful review of the EPA's conduct in this regard, the Court of Appeals adopted a "necessarily deferential" standard and affirmed. Pet. App. 7a, 15a. The Court of Appeals merely reviewed whether the EPA afforded "adequate consideration to all relevant evidence." Pet. App. 7a. Furthermore, the Court of Appeals did not engage in any meaningful review of whether the EPA correctly applied the "summary judgment-type" procedure. Rather, in direct contradiction of summary judgment standards, the Court of Appeals held that the very presence of competing expert opinions was "fatal" to petitioners' request for a hearing. Pet. App. 13a.

In addition, the Court of Appeals approved of the EPA's "Catch 22" timing rules, allowing the EPA to accept or reject evidence at will. The Court of Appeals not only allowed the EPA to discount as "recycled" arguments first presented before the EPA's proposed revocation order, but also to reject as "untimely" arguments first presented after the EPA's revocation order. Pet. App. 8a, 10a. The EPA's behavior in this regard was arbitrary and unreasona-

ble, and its approval by the Court of Appeals independently warrants this Court's review.

Most fundamentally, by permitting the agency to "consider" evidence and determine factual disputes without holding a hearing, the Court of Appeals has eviscerated the hearing requirement in 21 U.S.C. § 346a. The Court of Appeals' reasoning impermissibly grants federal agencies license to ignore express congressional mandates and their own express implementing regulations.

## III. THE COURT OF APPEALS' OPINION LIKELY WILL NEGATIVELY IMPACT INDUSTRY IN THE UNITED STATES.

The Court of Appeals' opinion likely will have a significant negative impact on American industrial concerns. Federal administrative agencies wield substantial power to regulate industry in the United States. Corporations rely on administrative agencies to provide a fair process prior to issuing regulations that may hamper or entirely preclude the development, production, and sale of all kinds of goods.

Through the comment and objection processes, industrial concerns are able to offer a wealth of practical experience and sector expertise to administrative agencies, positively influencing the development of federal regulations. But sometimes, the comment and objection processes are insufficient to permit full consideration of competing evidentiary claims. In recognition of this reality, Congress has provided — in certain circumstances — that administrative agencies should resolve material factual disputes through administrative hearings. American industry relies on such hearings to safeguard their interests in a broad range of regulatory contexts.

### A. American Industry Relies On The Right To A Hearing As A Fundamental Component Of The Administrative State.

Congress has woven the right to a hearing into the very fabric of the administrative state. The right to a hearing protects American industry and consumers from misinformed, ill-conceived regulation of a staggering array of products, including medical devices, prescription drugs, food and food additives, cosmetics, and consumer goods. Through participating in hearings, corporations are able to contribute a wealth of industry insight and practical experience to regulators. Even a cursory review of examples taken solely from the FFDCA demonstrates that hearings are a fundamental component of the administrative state, upon which myriad industrial concerns must rely.

For example, the pharmaceutical industry relies on hearing rights related to new drug applications.[4]

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[4] Correspondingly, the generic pharmaceutical industry relies on its hearing rights as to abbreviated new drug applications. An abbreviated new drug application "relies on the approved application of another drug with the same active ingredient to establish [its] safety and efficacy." 21 U.S.C. § 321. Congress has provided for a hearing following the denial of an abbreviated drug application based upon debarment. 21 U.S.C. § 335a(f)(3) (stating that "the Secretary shall provide . . . an opportunity for an informal hearing, to be held . . . on the decision of the Secretary to refuse approval of an abbreviated drug application"). Congress has also required a hearing before the FDA may withdraw approval for an abbreviated new drug application. 21 U.S.C. § 335c(b) (stating that the Secretary may not withdraw approval for an abbreviated drug application, on certain grounds, "unless the Secretary has issued an order for such action made on the record after opportunity for an agency hearing on disputed issues of material fact").

The research-based biopharmaceutical industry relies on the right to hearings "on the question whether such application is approvable." 21 U.S.C. § 355(c)(1)(B).

Innovator biopharmaceutical companies also rely on the right to a hearing prior to withdrawal of approval for a new drug application. *Id.* at § 355(e). As the Fourth Circuit held in *Hynson, Westcott & Dunning, Inc. v. Richardson*, 461 F.2d 215, 220 (4th Cir. 1972) as to 21 U.S.C. § 355(e), "[n]either due process nor the Administrative Practice Act permits an arbitrary denial [of a hearing] in any case where it can be fairly said there are genuine and substantial issues of fact in dispute."[5]

The food industry also relies on hearing rights provided by Congress. Congress has provided for a hearing when an allegedly adulterated or misbranded food product has been detained. 21 U.S.C. § 234(h)(4)(A) ("With respect to an article of food ordered detained . . . any person who would be entitled to be a claimant for such article . . . may appeal the order to the Secretary . . . the Secretary, after providing opportunity for an informal hearing, shall confirm or terminate the order").

Similarly, Congress has provided for a hearing prior to the reinstatement of a permit related to the manufacturing, processing, or packaging of food. 21 U.S.C. § 344(b) ("The Secretary is authorized to suspend immediately upon notice any permit . . . the Secretary shall, immediately after prompt hearing and an inspection of the establishment, reinstate

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[5] The Court of Appeals' opinion directly conflicts with the Fourth Circuit's holding in *Hynson*, 461 F.2d at 220.

such permit if it is found that adequate measures have been taken to comply with and maintain the conditions of the permit, as originally issued or as amended.").

Further, the food industry relies on its hearing rights as to the regulation of food additives. 21 U.S.C. § 348(f)(1) ("Within thirty days after publication of an order [regarding the regulation of food additives], any person adversely affected by such an order may file objections . . . and request[] a public hearing upon such objections. The Secretary shall, after due notice, as promptly as possible hold such public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections.").

Manufacturers and distributors of medical devices also rely on hearing rights provided by Congress. For example, the industry relies on hearing rights related to both the premarket approval of medical devices and recall. *See* 21 U.S.C. § 360e(e) (providing hearing right related to premarket approval of a medical device); *id.* at § 360h(e)(1) (providing hearing right related to the recall of a medical device).

The pesticide industry relies on other hearing rights in addition to the hearing right at issue in this case. For example, the industry relies on hearing rights related to the cancellation or reclassification of a pesticide's registration. *See* 7 U.S.C. § 136d(b)(2) (providing for "a hearing to determine whether or not [a pesticide's] registration should be canceled or its classification changed").

Such hearing rights provide American industrial concerns assurance that their interests will not be subjected to arbitrary or ill-considered regulation.

Thus, it is of considerable importance to American industry that the right to a hearing be upheld. Because the Court of Appeals' opinion undermines this fundamental right to a hearing, the Court of Appeals' opinion should be reversed.

### B. This Court's Review Is Warranted Because Numerous Governmental Agencies Employ A "Summary Judgment-type" Procedure When Determining Whether To Grant A Hearing.

In addition to generally undermining the right to a hearing, the Court of Appeals' opinion renders meaningless the "summary judgment-type" procedure used by the EPA to determine whether to hold a hearing. Worse, the damage wrought by the Court of Appeals' opinion likely will not be limited to that agency's actions.

Numerous other governmental agencies employ just such a "summary judgment-type" procedure in determining whether to hold a hearing. For example, the Food and Drug Administration employs a "summary judgment-type" procedure in determining whether to hold a hearing to resolve objections to certain regulations issued pursuant to the Fair Packaging and Labeling Act. 21 C.F.R. § 12.24 ("A request for a hearing will be granted if the material submitted shows . . . a genuine and substantial issue of fact for resolution at a hearing.").

The National Oceanic and Atmospheric Administration employs a "summary judgment-type" procedure when determining whether to hold a hearing with respect to a licensee's objection to a term in a deep seabed mining permit. 15 C.F.R. § 971.900(b) (referring to "[h]earings conducted under section

105(b)(3) of the Act on objection by a licensee or permittee to any term, condition or restriction in a license or permit, or to modification thereto, where the licensee or permittee demonstrates, after final action by the Administrator on the objection, that a dispute remains as to a material issue of fact").

The United States Department of Energy employs a "summary judgment-type" procedure in determining whether to grant a "trial-type hearing" for issues regarding the authorization to import or export natural gas. 10 C.F.R. § 590.313(a) ("The Assistant Secretary or presiding official shall grant a party's motion for a trial-type hearing, if the Assistant Secretary or presiding official determines that there is a relevant and material factual issue genuinely in dispute and that a trial-type hearing is necessary for a full and true disclosure of the facts.").

The Internal Revenue Service also employs a "summary judgment-type" procedure in determining whether to grant a taxpayer a hearing to review whether the taxpayer's property should be levied. *See* 26 C.F.R. § 301.6334-1(d)(2) ("The taxpayer will be granted a hearing to rebut the Government's prima facie case if the taxpayer files an objection within the time period required by the court raising a genuine issue of material fact demonstrating that the underlying tax liability has been satisfied, that the taxpayer has other assets from which the liability can be satisfied, or that the Service did not follow the applicable laws or procedures pertaining to the levy.").

Additionally, the Department of Transportation employs a "summary judgment-type" procedure in determining whether to grant a hearing upon appli-

cation for review of air carrier agreements. *See* 14 C.F.R. § 303.42 ("Requests for a formal oral evidentiary hearing must set out with specificity the material issues of fact in dispute that cannot be resolved without such a hearing.").

As these examples demonstrate, a "summary judgment-type" procedure is employed to determine whether to grant a hearing in remarkably diverse contexts throughout the federal government. Indeed, this "summary judgment-type" procedure is engrained in our administrative jurisprudence. Thus, it is crucially important that our governmental agencies apply this standard equitably, in a manner that comports with a basic understanding of "fair play and substantial justice." *Int'l Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945) (citation omitted).

The Court of Appeals' opinion teaches that, in resolving a dispute of fact, federal agencies are free to disregard statutory requirements and their own implementing regulations and exercise unfettered discretion in determining whether interested parties will be afforded a meaningful opportunity to be heard. The Court of Appeals' opinion allows an agency to decline to properly employ a "summary judgment-type" procedure when determining whether to hold a hearing. Given the prominence of the "summary judgment-type" procedures in agency processes and the practical significance of the District of Columbia Circuit's jurisprudence to the adjudication of disputes involving agency action, the Court of Appeals' opinion poses a significant likelihood of undermining the will of Congress and the due process rights of citizens and the commercial entities they create.

## CONCLUSION

For the foregoing reasons, the Court should grant the petition for a writ of certiorari and reverse the judgment of the United States Court of Appeals for the District of Columbia Circuit.

Respectfully submitted.

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IN THE

# Supreme Court of the United States

NATIONAL CORN GROWERS ASSOCIATION, *et al.*,
*Petitioners,*

v.

U.S. ENVIRONMENTAL PROTECTION AGENCY, *et al.*,
*Respondents.*

**On Petition for a Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit**

## BRIEF OF *AMICI CURIAE* CROPLIFE AMERICA AND AMERICAN FARM BUREAU FEDERATION IN SUPPORT OF PETITIONERS

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TABLE OF CONTENTS


| | Page |
|---|---|
| TABLE OF AUTHORITIES | iii |
| INTEREST OF *AMICI CURIAE* CROPLIFE AMERICA AND AMERICAN FARM BUREAU FEDERATION | 1 |
| INTRODUCTION AND SUMMARY OF ARGUMENT | 2 |
| BACKGROUND | 4 |
| A. Formal Versus Informal Rulemaking | 5 |
| B. Section 408's On-The-Record Hearing Requirement | 6 |
| C. The Origins Of EPA's Summary Judgment Procedure | 9 |
| REASONS FOR GRANTING THE PETITION | 13 |
| I. THE D.C. CIRCUIT IMPROPERLY DEFERRED TO EPA'S VIEW OF WHETHER CONGRESS MANDATED A HEARING IN THIS CASE | 14 |
| A. Deferring To Agency Hearing Denials Conflicts With This Court's Decision In *Hynson* | 14 |
| B. According Deference To A Hearing Denial Contravenes Congress's Purpose In Requiring On-The-Record Hearings | 15 |
| C. Deferring To Agency Hearing Denials Is Inconsistent With The Justification For Administrative Summary Judgment | 17 |
| II. THE ERRONEOUS DECISION BELOW RAISES AN IMPORTANT ISSUE OF ADMINISTRATIVE LAW | 20 |

TABLE OF CONTENTS—continued

Page

CONCLUSION ..... 23

# TABLE OF AUTHORITIES

CASES — Page

*Am. Paper Inst., Inc.* v. *Am. Electric Power Serv. Corp.*, 461 U.S. 402 (1983) ..... 5
*Anderson* v. *Liberty Lobby, Inc.*, 477 U.S. 242 (1986) ..... 20
*Eastman Kodak Co.* v. *Image Technical Serv., Inc.*, 504 U.S. 451 (1992) ..... 20
*FPC* v. *Texaco, Inc.*, 377 U.S. 33 (1964) ..... 15
*Ohio Bell Tel. Co.* v. *Pub. Utils. Comm'n of Ohio*, 301 U.S. 292 (1937) ..... 7
*Pactra Indus., Inc.* v. *Consumer Prod. Safety Comm'n*, 555 F.2d 677 (9th Cir. 1977) ..... *passim*
*United States* v. *Fla. E. Coast Ry.*, 410 U.S. 224 (1973) ..... 3, 6, 21
*United States* v. *Storer Broad. Co.*, 351 U.S. 192 (1956) ..... 15, 16
*Vt. Yankee Nuclear Power Corp.* v. *NRDC*, 435 U.S. 519 (1978) ..... 5, 6, 20, 21
*Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609 (1973) ..... *passim*

STATUTES AND REGULATIONS

Federal Food, Drug, and Cosmetic Act, ch. 675, 52 Stat. 1040 (1938) ..... 6, 7
Federal Food, Drug, and Cosmetic Act, ch. 559, 68 Stat. 511 (1954) ..... 8, 9
Federal Food, Drug, and Cosmetic Act, ch. 861, 70 Stat. 919 (1956) ..... 9
5 U.S.C. § 553 ..... 16
§ 556 ..... 3, 6, 16, 23
§ 706(2) ..... 5, 6
7 U.S.C. §§ 136-136y ..... 1
21 U.S.C. § 346a ..... 1, 13

TABLE OF AUTHORITIES—continued

Page

Reorganization Plan No. IV of 1940, 5 Fed.Reg. 2421 (June 29, 1940) ..... 8
Reorganization Plan No. 1 of 1953, 18 Fed.Reg. 2053 (Apr. 11, 1953) ..... 8
35 Fed.Reg. 7250 (May 8, 1970)..... 10, 18
Reorganization Plan No. 3 of 1970, 35 Fed.Reg. 15623 (Oct. 6, 1970)..... 8
40 Fed.Reg. 22950 (May 27, 1975).. 11, 12, 18, 19
41 Fed.Reg. 51706 (Nov. 23, 1976) ..... 12, 18, 19
53 Fed.Reg. 41126 (Oct. 19, 1988) ..... 12, 13, 18

LEGISLATIVE HISTORY

H.R. Rep. No. 75-2139 (1938) ..... 7, 16
H.R. Rep. No. 75-2716 (1938) (Conf. Rep.)... 7
H.R. Rep. No. 104-669(I) (1996)..... 13
S. Rep. No. 83-1635 (1954), *reprinted in* 1954 U.S.C.A.A.N. 2626 ..... 7, 8, 9, 22

SCHOLARLY AUTHORITIES

1 Pierce, Jr., *Administrative Law Treatise* (4th ed. 2002)..... 5, 21
Gellhorn & Robinson, *Summary Judgment in Administrative Adjudication*, 84 Harv. L. Rev. 612 (1971) ..... 9, 10, 18
Hamilton, *Rulemaking on a Record by the Food and Drug Administration*, 50 Tex. L. Rev. 1132 (1972) ..... 11

## INTEREST OF *AMICI CURIAE* CROPLIFE AMERICA AND AMERICAN FARM BUREAU FEDERATION[1]

CropLife America (CropLife) is the national voice of the agricultural crop protection industry. It represents the companies that develop, manufacture, and distribute virtually all crop protection and biotechnology products used by American farmers. Many of those products are regulated by the United States Environmental Protection Agency (EPA) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. §§ 136-136y, which establishes certain requirements for the sale and use of pesticides, and section 408 of the Federal Food, Drug, and Cosmetics Act (FFDCA), 21 U.S.C. § 346a, which governs the issuance, modification, and revocation of pesticide tolerances (i.e., maximum allowable residue limits) needed for lawful sale of raw agricultural commodities treated with particular pesticides. CropLife frequently participates as *amicus curiae* in cases, like this one, that raise significant issues under FIFRA and FFDCA § 408.

American Farm Bureau Federation (AFBF) is a voluntary general farm organization formed in 1919 to protect, promote, and represent the business, economic, social, and educational interests of American farmers. AFBF represents more than 6.2

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[1] Pursuant to Supreme Court Rule 37.6, *amici curiae* state that no counsel for any party authored this brief in whole or in part and that no entity or person, aside from *amici curiae*, its members, and its counsel, made any monetary contribution toward the preparation or submission of this brief. Pursuant to Supreme Court Rule 37.2, counsel of record for all parties received timely notice of *amici curiae*'s intent to file this brief. Petitioners and respondents have consented to the filing of this brief, as reflected in letters filed with the Clerk of Court.

million member families through member organizations in all fifty states and Puerto Rico. Many of the AFBF member families own and operate farms that produce the crops, livestock, and poultry that provide safe and affordable food, fuel, and fiber for Americans and a growing global population. Many of those farms use crop protection products registered under FIFRA as an essential tool for eliminating pests, weeds, and fungi that would otherwise devastate our nation's food supply.

## INTRODUCTION AND SUMMARY OF ARGUMENT

This case raises fundamentally important issues of administrative law warranting this Court's review. In the decision below, the D.C. Circuit erroneously applied a highly deferential standard of review to an agency's refusal to conduct a statutorily-mandated on-the-record hearing. In doing so, the D.C. Circuit took deference principles used to review policy judgments adopted through informal rulemaking and improperly extended those principles to review of a profoundly different question—*i.e.*, whether an agency properly refused to conduct formal rulemaking that Congress required as an essential check on the agency's authority. According deference to such an agency refusal is incompatible with administrative summary judgment standards. It is also flatly inconsistent with this Court's decision upholding such procedures, with Congress's purpose in requiring on-the-record hearings, and with the historical justifications offered for agency use of summary judgment procedures.

The decision below seeks to promote agency convenience and efficiency in an area where Congress has consciously struck a different balance. Despite

the pronounced trend toward greater use of informal rulemaking ushered in by this Court's seminal decision in *United States* v. *Florida East Coast Railway*, 410 U.S. 224 (1973), Congress has adhered to its initial decision nearly 75 years ago to require on-the-record hearings in regulatory schemes that, like § 408, empower agencies to ban potentially harmful products. Congress has done so because such regulatory power creates the risk that overbroad enforcement will result in bans of safe and useful products, to the detriment of manufacturers and users alike. Indeed, that is precisely what happened here: EPA effectively banned use of carbofuran, despite the fact that there has never been a documented incident of any person suffering adverse health effects from dietary exposure to carbofuran, either from food or drinking water. Pet. 7-8. As this very case illustrates, therefore, on-the-record hearings serve as an essential check against the danger of overbroad enforcement by ensuring that products are banned only after "a full and true disclosure of the facts." 5 U.S.C. § 556(d).

By deferring to an agency's decision to free itself of an essential check on its power, the D.C. Circuit effectively overrode Congress's judgment and the careful balance it struck. In 1954, Congress responded to concerns about the burdens of using formal rulemaking to set tolerances by adopting a hybrid, two-stage scheme: EPA may use informal rulemaking to develop or revoke a proposed tolerance, but on-the-record hearings are required if an affected party objects and raises material issues of disputed fact. EPA and the D.C. Circuit evidently believe that this scheme is inefficient, and that the results of the informal rulemaking stage should not even be questioned unless EPA acts arbitrarily and

capriciously in refusing to conduct a hearing. Indeed, in addition to deferring to EPA's hearing denial decision, the D.C. Circuit also blessed the agency's (illogical) rules that hearing requests can neither "recycle" issues from the informal rulemaking stage nor present issues that were not raised during that stage. Collectively, these principles convert Congress's two-stage hybrid scheme into something entirely different—informal rulemaking, with an extremely limited right to "administrative rehearing."

Review is thus warranted not only because the decision below conflicts with the decision of this Court and decisions by other courts of appeals, but because it raises a fundamentally important issue of administrative law. Congress has used this same two-stage, hybrid scheme in several statutes empowering agencies to ban products, and the vast majority of agency decisions are subject to review in the D.C. Circuit. Accordingly, this Court should, as it has several times in the past, grant certiorari to correct a fundamental error in administrative law by the highly influential D.C. Circuit.

## BACKGROUND

We will not repeat here the statutory scheme under which this case arises, the proceedings before EPA, or the decision below, all of which are ably presented in the petition. Instead, because the central flaw in the decision below was the D.C. Circuit's extension of inapposite deference principles to an agency's decision to dispense with a statutorily-required on-the-record hearing, we highlight at the outset the essential differences between informal and formal rulemaking. We then discuss the origins and rationale behind the on-the-hearing requirement of § 408 of the FFDCA, as well as the development of

administrative summary judgment procedures, including the procedure governing proceedings to establish pesticide tolerances. A full understanding of this background makes clear the glaring errors in the decision below.

### A. Formal Versus Informal Rulemaking.

Informal rulemaking is accomplished through the notice and comment process set forth in § 553 of the Administrative Procedure Act (APA). Agencies conducting informal rulemakings need not hold oral hearings at all. *Vt. Yankee Nuclear Power Corp.* v. *NRDC*, 435 U.S. 519, 547 (1978). Instead, "[a]bsent constitutional constraints or extremely compelling circumstances," they are "free to fashion their own rules of procedure and to pursue methods of inquiry capable of permitting them to discharge their multitudinous duties." *Id.* at 543 (internal quotations omitted). Moreover, absent an explicit directive in the agency's organic statute, the factual predicates for rules adopted through informal rulemaking are reviewed under the arbitrary and capricious standard, see 5 U.S.C. § 706(2)(A), which is "more lenient" than the "substantial evidence" standard. *Am. Paper Inst., Inc.* v. *Am. Electric Power Serv. Corp.*, 461 U.S. 402, 412 n.7 (1983).

Where a statute mandates formal rulemaking, "the agency must conduct an oral evidentiary hearing that is closely analogous to the oral evidentiary hearing that takes place in judicial adjudications of disputes between individuals." Pierce, Jr., *Administrative Law Treatise* § 7.1, at 412 (4th ed. 2002). This trial-like procedure affords affected parties the right to an "impartial" fact-finder, as well as the right to present "oral or documentary evidence, to submit rebuttal evidence, and to conduct such cross-examination as may be required for a full and true disclosure of the

facts." 5 U.S.C. § 556(b)&(d). The findings underlying rules adopted through formal rulemaking are subject to the "substantial evidence" standard of review, *id.* § 706(2)(E), not merely the "more lenient" arbitrary and capricious standard.

As a result of this Court's decision in *Florida East Coast*, the more protective requirements of formal rulemaking are limited to those statutory schemes that require rules to be made "'on the record after opportunity for an agency hearing,'" or use "other statutory language having the same meaning." 410 U.S. at 237-38. Absent such language, agencies are free to use informal notice-and-comment rulemaking, and this Court has rebuffed lower court efforts to mandate additional procedures for informal rulemaking. *Vt. Yankee*, 435 U.S. at 543-48. The Court made clear in *Florida East Coast*, however, that neither courts nor agencies may dispense with formal rulemaking procedures when Congress clearly requires them. *Fla. E. Coast*, 410 U.S. at 238 (citing § 701(e) of the FFDCA as an example of a statute that mandates formal rulemaking).

### B. Section 408's On-The-Record Hearing Requirement.

In 1938, Congress enacted a statutory scheme to establish or revoke tolerances for pesticides found on foods. See FFDCA, ch. 675, § 406, 52 Stat. 1040, 1049 (1938). Congress required the Secretary of Agriculture to establish by regulation tolerances limiting the quantity of pesticides to a level safe for human consumption. *Id.* § 406(a), 52 Stat. at 1049. Such regulations were to be promulgated under § 701(e) of the Act, which provided that the Secretary "shall hold a public hearing upon a proposal to issue, amend, or repeal any regulation." *Id.* § 701(e), 52 Stat. at 1055. Congress provided that "any interested

person may be heard" at the hearing, and that the Secretary shall base "his order only on substantial evidence of record at the hearing." *Id.*

The requirement of an on-the-record hearing was central to the law. A House Report states that if the Secretary's order establishing or revoking a tolerance under the FFDCA "is to be valid, the Government must have placed in the record at the hearing its evidence in support of the action taken and thereby afford opportunity for persons affected to controvert viva voce the Government's evidence." H.R. Rep. No. 75-2139, at 10 (1938). Citing this Court's then-recent decision in *Ohio Bell Telephone Co.* v. *Public Utilities Commission of Ohio*, 301 U.S. 292 (1937), which addressed the critical role of hearings in preventing arbitrary government action, the Report continued: "it is essential to such a hearing that all the evidence on which the administrative officer acts be disclosed at the hearing and that the right to controvert viva voce be accorded." H.R. Rep. No. 75-2139, at 10; see also H.R. Rep. No. 75-2716, at 25 (1938) (Conf. Rep.) ("Secretary must base an order only on substantial evidence of record"). As then-Judge Kennedy noted, the drafters of § 701(e) considered public hearings "an essential procedure, and ... they intended the broad grant of power given to the administrative body by the statute to be checked by judicial review based only on the record compiled at the public hearings." *Pactra Indus., Inc.* v. *Consumer Prod. Safety Comm'n*, 555 F.2d 677, 682 (9th Cir. 1977).

Ultimately, the requirement that all tolerances be established through formal rulemaking proved burdensome to all concerned. See S. Rep. No. 83-1635 (1954), *reprinted in* 1954 U.S.C.A.A.N. 2626, 2627 (noting costs "to Government, to industry, [and] to agricultural organizations" of setting tolerances for

vegetables and fruits). In 1954, Congress responded by enacting a new two-tiered regulatory scheme.

Under the first tier, a proposed tolerance is developed through "informal proceedings rather than the formal public hearing type of proceedings." *Id.* at 2629. The Secretary of Health, Education, and Welfare, who had inherited responsibility for establishing tolerances,[2] would issue the tolerance within a specified time after giving notice of the proposal. FFDCA, ch. 559, § 408(d)(1)-(2), (e), 68 Stat. 511, 512-13, 514 (1954) (enacting 21 U.S.C. § 346a (1954)). Within a specified time thereafter, any party who submitted a petition for registration of a tolerance could request the tolerance be reviewed by a scientific advisory committee. *Id.* § 408(d)(2), (e), 68 Stat. at 512-13, 514. The committee had deadlines for issuing a report, and the Secretary then had 30 days to issue a final order. *Id.* § 408(d)(3), (e), 68 Stat. at 513, 514. The resulting regulation was "effective upon publication." *Id.* § 408(d)(4), (e), 68 Stat. at 513, 514.

While streamlining the process for initial tolerance determinations, however, Congress preserved affected parties' rights to an on-the-record hearing. Any person "adversely affected by a [tolerance] regulation" could file an objection and request a hearing. *Id.* § 408(d)(5), 68 Stat. at 513. In response,

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[2] The functions of the Food and Drug Administration were transferred from the Department of Agriculture to the Federal Security Agency, *see* Reorganization Plan No. IV of 1940, 5 Fed.Reg. 2421, § 12, at 2444 (Jun. 29, 1940), and then to the Department of Health, Education, and Welfare, *see* Reorganization Plan No. 1 of 1953, 18 Fed.Reg. 2053, § 5, at 2053 (Apr. 11, 1953). They were later transferred to EPA. Reorganization Plan No. 3 of 1970, 35 Fed.Reg. 15623, § 2(a)(4), at 15624 (Oct. 6, 1970).

the Secretary was required to "hold [a] public hearing for the purpose of receiving evidence relative and material to the issues raised by such objections." *Id.* After the hearing, the Secretary had to "act upon such objections" and issue a regulation "based only on substantial evidence of record at such hearing." *Id.* at 513-14. Thus, Congress reduced the number of on-the-record hearings by "limiting such hearings to issues which may remain in dispute at the conclusion of the informal proceedings." S. Rep. No. 83-1635, *reprinted in* 1954 U.S.C.A.A.N. at 2629-30. But, "[w]here the informal procedures do not produce a satisfactory tolerance or exemption the rights of all concerned to a full and fair hearing on the disputed issues [was] preserved." *Id.* at 2630; see also *id.* at 2634 (formal rulemaking required "on those parts of tolerance or exemption regulations to which objection is made").[3]

### C. The Origins Of EPA's Summary Judgment Procedure.

a. In 1970, as a way of ameliorating chronic administrative backlogs, the Administrative Conference of the United States proposed use of summary-judgment procedures in "'adjudicatory or rulemaking proceeding[s] required by statute to be determined on the record after opportunity for agency hearing.'" Gellhorn & Robinson, *Summary Judgment in Administrative Adjudication*, 84 Harv. L. Rev. 612, 628 (1971) (quoting Admin. Conference of the U.S., *Recommendation 20: Summary Decision in Agency Adjudication* (adopted June 2-3, 1970)). The recommendation was modeled on Federal Rule of

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[3] Two years later, Congress adopted a very similar two-tier scheme for all regulations issued under § 701(e). *See* Ch. 861, sec. 2, § 701(e), 70 Stat. 919, 919 (1956).

Civil Procedure 56 and borrowed its operative standard virtually verbatim. See *id.* (agency may grant summary decision "'if the pleadings, affidavits, material obtained by discovery or otherwise, or matters officially noticed, show that there is no genuine issue as to any material fact'") (quoting *Recommendation 20*).

A number of agencies initially objected to this proposal on the ground that the procedure would abridge statutory rights to hearings. *Id.* at 616. The proposal's drafters—Gellhorn and Robinson—responded to this and similar objections by repeatedly stressing that "[t]he proposed rule, like Rule 56, would not displace full hearings where basic facts are in dispute." *Id.* at 618; see also *id.* at 616 (under the governing standard of Rule 56, "summary judgment is granted only when the papers filed with the motion clearly reveal that an evidentiary hearing would serve no useful purpose").

b. As the Administrative Conference was formulating this proposal, FDA adopted a summary judgment procedure for on-the-record proceedings mandated under 1962 amendments to the FFDCA. Under these amendments, FDA was authorized to withdraw pre-1962 drug approvals if it found, after notice and an opportunity for a hearing, that there was "a lack of substantial evidence" of a drug's effectiveness. FDA issued regulations that specified the types of scientific studies required to establish effectiveness, and authorized the denial of a hearing when it "clearly appears ... from the reasons and factual analysis in [a] request for [a] hearing that there is *no genuine and substantial issue of fact* which precludes" withdrawal of the prior approval. See 35 Fed.Reg. 7250, 7252 (May 8, 1970) (emphasis added). See also *id.* at 7251 (noting that this

regulation was "an adaptation of the summary judgment procedures of the U.S. District Courts"). This Court upheld this summary judgment procedure and standard in *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609 (1973).

In 1975, FDA proposed the summary judgment standard that would later serve as the model for the standard at issue in this case. Citing legal commentary on and discussion of, *inter alia*, the Administrative Conference proposal,[4] and explaining that it had "carefully considered all of the comments and suggestions made in ... these reports and discussions," 40 Fed.Reg. 22950, 22966 (May 27, 1975), FDA proposed a summary judgment standard for public hearings required under § 701(e) of the FFDCA. Under this standard, an on-the-record hearing was required if a requester showed:

> (1) that "[t]here is a genuine and substantial issue of material fact for resolution at a hearing";
>
> (2) that this "factual issue is capable of being resolved by available and specifically identified reliable evidence";
>
> (3) that this evidence, "if established at a hearing, would be adequate to justify resolution of the factual issue in the way sought by" the requester; and
>
> (4) that such a resolution "is adequate to justify the action requested."

*Id.* at 23001. FDA explained that, under this standard, "a hearing will be denied *only* where there

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[4] *See* 40 Fed.Reg. 22950, 22966 (May 27, 1975) (citing Hamilton, *Rulemaking on a Record by the Food and Drug Administration*, 50 Tex. L. Rev. 1132, 1183 & n.156 (1972), which discussed the Administrative Conference proposal).

is *no* relevant factual issue in dispute." *Id.* at 22968 (emphases added).

In response to comments, FDA again stated that a requester "must show only that there exist factual issues whose resolution is material to the outcome of the proceeding." 41 Fed.Reg. 51706, 51708 (Nov. 23, 1976). In addition, it stressed that the:

> [e]valuation of an objection or request for hearing ... *does not involve determining the weight and credibility of relevant evidence*; it involves determining whether there are factual issues to be resolved at a hearing. The regulation makes clear that establishing the validity of the data and information identified in an objection or request for hearing *is the function of the hearing.*

*Id.* at 51708 (emphases added). See also *id.* at 51709-10 (in ruling upon a request, agency would not "attempt to determine whether the evidence identified is credible or sufficient," nor will it "evaluate the probative value of the evidence identified in the objection"). Finally, FDA explained that the requirement of identifying available evidence in support of an objection was "not intended to limit evidence at the hearing to that identified in the objection." *Id.* at 51707. See also *id.* at 51709 ("additional relevant and probative evidence may be introduced at the hearing.").

c. In 1988, EPA adopted the summary judgment regulations applied in this case. EPA explained that these regulations were, "[t]o a very large extent, ... based on FDA regulations" promulgated in 1975. 53 Fed.Reg. 41126, 41129 (Oct. 19, 1988). EPA stated that, "[t]o the extent that the language in the regulations now proposed ... is the same as or

substantively similar to FDA regulations, EPA relies on FDA's explanations in support of this proposal and refers readers to them." *Id.* (citing Federal Register entries discussed above). And, EPA explained, the "rules for deciding whether to hold a hearing [under § 408] are substantially similar to the FDA rules." *Id.* See also App. 82a-83a (same).

Finally, in 1996, Congress amended the FFDCA and FIFRA in order to "establish a single regulatory framework for both raw and processed foods." H.R. Rep. No. 104-669(I), at 59 (1996). As part of this overhaul, Congress amended § 408 to provide that, in response to objections to a tolerance or revocation, EPA

> shall, upon the initiative of the Administrator or upon the request of an interested person and after due notice, hold a public evidentiary hearing if and to the extent the Administrator determines that such public hearing is necessary to receive factual evidence relevant to material issues of fact raised by the objections.

21 U.S.C. § 346a(g)(2)(B). This amendment thus codified the summary judgment standard EPA had adopted 18 years earlier. Indeed, following the 1996 amendments, EPA maintained the same summary judgment regulations that it had promulgated in 1988.

## REASONS FOR GRANTING THE PETITION

In the decision below, the D.C. Circuit did not simply reach an erroneous result through the application of settled rules to a unique set of facts. Instead, the lower court reviewed EPA's decision in this case under the *wrong* legal standard. This fundamental error warrants review by this Court.

## I. THE D.C. CIRCUIT IMPROPERLY DEFERRED TO EPA'S VIEW OF WHETHER CONGRESS MANDATED A HEARING IN THIS CASE.

### A. Deferring To Agency Hearing Denials Conflicts With This Court's Decision In *Hynson*.

The D.C. Circuit's decision to accord substantial deference to EPA's decision to dispense with an on-the-record hearing requirement conflicts with this Court's decision in *Hynson*. As noted, in 1970 FDA adopted a summary judgment standard for revocation of pre-1962 drug approvals. Although this Court upheld the regulation, it affirmed a Fourth Circuit decision rejecting one of the agency's first applications of that standard.

Critically, this Court noted that agency findings in support of a hearing denial were *not* subject to review under the APA's deferential "substantial evidence" test. That test, the Court explained, applies after an agency has *conducted* an on-the-record hearing under §§ 556 and 557 of the APA, not where the issue on appeal "involves the initial agency determination whether a hearing is required by statute." 412 U.S. at 623 n.19. Instead, in reviewing a hearing denial, courts must determine whether the agency's "findings accurately reflect the [evidence submitted in support of a hearing request] and if they do, whether the deficiencies [the agency] finds conclusively render the study inadequate" under the relevant regulatory standards. *Id.* at 622.

This is plainly not a highly deferential method of review. Rather than defer to an agency's findings, courts must ensure that the agency "accurately" evaluated an objector's evidence to determine

whether the agency has properly concluded "that the application cannot succeed," *id.* at 621, based on the evidence proffered. This standard of review, which is akin to that used to assess whether a district court properly entered summary judgment,[5] ensures that the purpose of an on-the-record hearing is not thwarted.

In the decision below, the D.C. Circuit declined to undertake the review that *Hynson* requires. Rather than determine whether EPA accurately evaluated the evidence proffered for a hearing, the lower court refused to substitute its judgment for that of the agency. App. 7a. This deferential, "hands-off" approach cannot be reconciled with the judicial review this Court required in conjunction with its decision to uphold agency use of summary judgment procedures. The decision below thus warrants review for this reason alone.

### B. According Deference To A Hearing Denial Contravenes Congress's Purpose In Requiring On-The-Record Hearings.

The decision in this case should also be reviewed because it thwarts the very purpose of statutorily-mandated on-the-record hearings. Congress mandated such a hearing in § 408 and in other statutes to serve as a restraint on agency power and to ensure that products are banned only after a full a fair disclosure of all relevant facts. Given these purposes, agencies are plainly not entitled to

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[5] This standard is also consistent with the Court's earlier decisions in *United States* v. *Storer Broadcasting Co.*, 351 U.S. 192 (1956) and *FPC* v. *Texaco Inc.*, 377 U.S. 33, 39-45 (1964). There, the Court upheld agency decisions to issue, through informal rulemaking, bright-line qualification rules and to deny hearings to those who manifestly could not satisfy those rules.

deference—let alone substantial deference—when they decide to dispense with these restraints.

As § 408's history makes clear, the purpose of the on-the-record hearing requirement is to protect persons affected by agency regulation. In authorizing the establishment and revocation of tolerances, Congress deemed it "essential" "that all the evidence on which the administrative officer acts be disclosed at the hearing and that the right to controvert viva voce be accorded." H.R. Rep. No. 75-2139, at 10. Public hearings followed by judicial review were thus designed as an "essential" "check[]" on "the broad grant of power given to the administrative body by the statute." *Pactra Indus.*, 555 F.2d at 682.

This same understanding animates the APA, which was enacted eight years after Congress first authorized the setting or revocation of tolerances through formal rulemaking. Section 553 provides that "[w]hen rules are ... to be made on the record after an opportunity for an agency hearing"—the requirement set forth in § 701(e) of the FFDCA in 1938—then "sections 556 and 557 of this title apply." 5 U.S.C. § 553. These latter provisions mandate use of an "impartial" presiding officer, and confer the right to present "oral or documentary evidence, to submit rebuttal evidence, and to conduct such cross-examination as may be required *for a full and true disclosure of the facts*." *Id.* § 556(b)&(d) (emphasis added). Indeed, shortly after Congress carried forward § 701(e)'s hearing requirement in the two-stage rulemaking process it adopted for tolerances in 1954, this Court described the APA's hearing standards as "essential for wise and just application of the authority of administrative boards and agencies." *United States* v. *Storer Broad. Co.*, 351 U.S. 192, 202 (1956). See also *Pactra Indus.*, 555

F.2d at 685 (formal rulemaking mandated by § 701(e) of the FFDCA and the APA "impose[s] a discipline on the agency's decision-making process," fosters "a better understanding of the problem at hand," and results in "a more refined and precise statement of agency policy").

It simply makes no sense to defer to an agency's decision to dispense with an on-the-record hearing requirement that is supposed to serve as an essential *check* on that agency's exercise of discretion. Deference is appropriate when an agency exercises discretion that Congress has conferred, not when it decides that limits Congress has placed on its discretion do not apply. The D.C. Circuit's application of deference in this case, therefore, is utterly antithetical to Congress's purpose in creating the hearing requirement.

### C. Deferring To Agency Hearing Denials Is Inconsistent With The Justification For Administrative Summary Judgment.

Deferring to an agency hearing denial is also antithetical to the very premise of summary judgment and the justifications for agency use of that device. A trial court's decision to dispense with a trial is not subject to deferential "abuse of discretion" review. This is because a litigant's right to a trial is not a matter of judicial discretion but is instead mandated by a provision in the organic charter that creates Article III courts. The same logic applies here. Where an agency's organic statute mandates an on-the-record hearing, an affected person's right to that hearing is not a matter of agency discretion. Thus, to ensure that an agency's grant of summary judgment does not abridge a right conferred by the decision-maker's organic charter, that decision

likewise should not be reviewed under a highly deferential standard.

Proponents of administrative summary judgment recognized and repeatedly invoked this very parallel. The drafters of the Administrative Conference recommendation explained that, "[j]ust as summary judgment is not in conflict with the right to a trial by jury," administrative summary judgment "honors the right to" an on-the-record hearing. Gellhorn & Robinson, *supra*, at 616. This was so, they explained, because "[t]he proposed rule, like Rule 56, would not displace full hearings where basic facts are in dispute." *Id.* at 618. Similarly, in proposing its summary judgment standard for revocation of pre-1962 drug approvals, FDA explained that the standard was "an adaptation of the summary judgment procedures of the U.S. District Courts." 35 Fed.Reg. at 7251. And, when FDA later adopted the summary judgment standard for regulations issued under § 701(e), it relied on the Administrative Conference's proposed rule and accompanying commentary, 40 Fed.Reg. at 22966, and repeatedly explained that, under this standard, "a hearing will be denied *only* where there is *no* relevant factual issue in dispute," *id.* at 22968 (emphases added). See also 41 Fed.Reg. at 51708. EPA, in turn, adopted this same standard in its regulations, as well as FDA's rationale and explanation for that standard. 53 Fed.Reg. at 41129.

Significantly, while proponents of administrative summary judgment made clear that hearings would not be required on issues of policy (where agencies

enjoy discretion),[6] they nowhere claimed that agencies could exercise discretion in deciding whether genuine and substantial issues of fact were in dispute. To the contrary, FDA repeatedly stated that its summary judgment regulation under § 701(e) was appropriate because the agency's "[e]valuation of an objection or request for hearing ... *does not involve determining the weight and credibility of relevant evidence.*" 41 Fed.Reg. at 51708 (emphasis added). Accordingly, FDA assured the public that it would "not, in ruling upon a request [for a hearing], attempt to determine whether the evidence identified is credible or sufficient," or "evaluate the probative value of the evidence identified in the objection." *Id.* at 51709-10.

The D.C. Circuit's decision reflects no appreciation for this history, and could not be more inconsistent with it. Under the lower court's deferential standard of review, "'differences in the weight or credence given to particular scientific studies ... are insufficient'" grounds for disturbing a hearing denial, and courts reviewing such a denial are not to "'substitute [their] judgment on highly technical and factual matters for that of the agency.'" App. 7a. Yet the agency that promulgated the standard stressed that it had no discretion to weigh or evaluate evidence in deciding whether to hold a hearing, because "establishing the validity of the data and information identified in an objection or request for hearing *is the function of the hearing.*" 41 Fed.Reg. at 51708 (emphasis added).

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[6] *See, e.g.*, 40 Fed.Reg. at 22968 ("[i]f there are only policy or legal issues involved, rather than factual issues, there is no requirement that a hearing be held").

FDA's representations and disclaimers, which EPA has embraced as its own, are consistent with judicial practice under Rule 56. There, courts likewise cannot weigh or evaluate the relative strength of evidence in deciding whether to grant summary judgment and must instead draw all inferences in favor of a litigant opposing such a grant. *Anderson* v. *Liberty Lobby, Inc.*, 477 U.S. 242, 249, 255 (1986). Just as a district court's non-discretionary decision to grant summary judgment is not properly reviewed under a deferential abuse-of-discretion standard, see *Eastman Kodak Co.* v. *Image Technical Servs., Inc.*, 504 U.S. 451, 465 n.10 (1992), so too an agency's equally non-discretionary decision to dispense with a statutorily required on-the-record hearing is not properly reviewed under a deferential arbitrary and capricious standard. Simply put, in deciding whether to hold a hearing, an agency cannot weigh or evaluate evidence. And thus, no deference is owed to the "weight or credence" an agency gives to particular evidence or any judgments it reaches on "factual matters" in the course of deciding not to hold a hearing.

## II. THE ERRONEOUS DECISION BELOW RAISES AN IMPORTANT ISSUE OF ADMINISTRATIVE LAW.

The conflict the D.C. Circuit's decision creates with *Hynson*, as well as with decisions by several courts of appeals, see Pet. at 23-26, justifies review by this Court. Even absent conflicts, however, this Court has reviewed decisions raising important questions of administrative law. See, *e.g.*, *Vt. Yankee*, 435 U.S. at 525, 536 n.14 (granting review of D.C. Circuit decisions out of "concern that they had seriously misread or misapplied ... statutory and decisional law" and because "the vast majority of challenges to

administrative agency action are brought" in that circuit).[7] It should do the same here to provide a necessary correction to administrative law in the D.C. Circuit.

As a result of this Court's "revolutionary holding in *Florida East Coast*," formal rulemaking is now restricted to statutes that clearly require on-the-record hearings. See 1 Pierce, *supra*, § 7.2, at 420. And this Court has repudiated efforts to mandate additional procedures for informal rulemaking. *Vt. Yankee*, 435 U.S. at 543-48. Yet, despite the well-documented burdens of formal rulemaking, see 1 Pierce, *supra*, § 7.2, at 420, Congress has continued to require on-the-record hearings in various regulatory schemes, including this one. Such proceedings have been made more efficient by this Court's approval of administrative summary judgment, *Hynson*, 412 U.S. at 618-22, and by the streamlining achieved through the two-tier scheme Congress adopted in this and other regulatory schemes. See *Pactra Indus.*, 555 F.2d at 683-85 (discussing similar two-stage process for banning of hazardous substances). The decision below, however, plainly swings the pendulum too far in favor of agency convenience and efficiency, at the expense of important interests that Congress sought to protect.

It may well appear to the D.C. Circuit and EPA that revoking tolerances is an exercise in weighing "legislative" facts, and that the results of the informal rulemaking stage should be disturbed only where

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[7] *See also Fla. E. Coast*, 410 U.S. at 236 & n.6 (noting probable jurisdiction despite unanimity of lower courts, fact that lower courts had not had a chance to address intervening Court authority, and government's failure to press the issue in proceedings below).

EPA fails to give "adequate consideration to all relevant evidence in the record." App. 7a. But this is manifestly not the scheme Congress adopted. Congress viewed public hearings followed by judicial review as an "essential" "check[]" on "the broad grant of power given to the administrative body by the statute." *Pactra Indus.*, 555 F.2d at 682. And, in response to evidence that use of such hearings to establish or revoke tolerances could be unduly burdensome, it *retained* the requirement with respect to "those parts of tolerance or exemption regulations to which objection is made." S. Rep. No. 83-1635, *reprinted in* 1954 U.S.C.A.A.N. at 2634.

Congress has repeatedly recognized that the power to ban pesticides, ineffective drugs, or hazardous substances carries with it the risk that overbroad enforcement will result in the ban of safe and useful products. Such bans, in turn, can harm legitimate reliance and other interests of affected parties. As Justice Powell observed with respect to FDA's authority to revoke pre-1962 drug approvals for ineffective drugs, "[i]n an understandable zeal to remove [such products], an administrative agency must not overlook both the interest of the public and the right of the proprietor in protecting the drugs that are useful." *Hynson*, 412 U.S. at 639 n.2 (Powell, J., concurring in part).

The same is true here. The laudable desire to eliminate harmful pesticide residues can (and in this case did) lead EPA to ban safe and useful products. As noted, there has never been a documented incident of adverse health effects from dietary exposure to carbofuran, even during the 1980s, when annual usage was 50 times what it is today. See Pet. at 7-8; App. 344a-45a. Banning useful products like this is detrimental not only to manufacturers, but to

the growers who rely on those products and have invested time and money in the unique equipment, protective gear, and training needed to use those products. On-the-record hearings prevent precisely these types of harms, by ensuring the "full and true disclosure of the facts," 5 U.S.C. § 556(d), that fosters "a better understanding of the problem at hand," and "a more refined and precise statement of agency policy." *Pactra Indus.*, 555 F.2d at 685. Because the decision below has effectively gutted this Congressionally-mandated protection in § 408, and threatens to do the same to similar statutory schemes that empower agencies to ban products, this Court should review and reverse the decision below.

## CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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No. 10-1031

In the
# Supreme Court of the United States

NATIONAL CORN GROWERS ASSOCIATION, et al.,
*Petitioners*,
v.
U.S. ENVIRONMENTAL PROTECTION AGENCY, et al.,
*Respondents*.

On Petition for Writ of Certiorari to United States Court of Appeals for the District of Columbia Circuit

## BRIEF AMICUS CURIAE OF PACIFIC LEGAL FOUNDATION AND THE CATO INSTITUTE IN SUPPORT OF PETITIONERS NATIONAL CORN GROWERS ASSOCIATION, ET AL.

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## QUESTIONS PRESENTED

Does the Environmental Protection Agency have sole discretion to ban a product without an evidentiary hearing required by federal law and the agency's own regulations?

Should the D.C. Circuit have deferred to the EPA without any independent review, in conflict with its sister courts and long-standing Supreme Court precedent?

## TABLE OF CONTENTS

Page

QUESTIONS PRESENTED . . . . . i

TABLE OF AUTHORITIES . . . . . iii

IDENTITY AND INTEREST OF AMICI . . . . . 1

INTRODUCTION . . . . . 2

STATEMENT OF THE CASE . . . . . 4

SUMMARY OF ARGUMENT . . . . . 7

ARGUMENT . . . . . 8

A. Review Is Warranted Because the Lower Court Undermined the Legal Requirement for a Hearing Under the FFDCA . . . . . 8

B. Review Is Warranted To Establish the Proper Standard of Review Under the FFDCA for a Public Hearing . . . . . 11

C. Review Is Warranted To Curtail Abuse of the Administrative Process . . . . 14

D. Review Is Warranted To Establish That Complete Deference Is Not Compatible with a Summary-Judgment-Type Proceeding . . . . . 18

CONCLUSION . . . . . 20

# TABLE OF AUTHORITIES

Page

*Cases*

*Chevron v. Natural Resources Defense Council*, 467 U.S. 837 (1984) . . . . . 9

*Community Nutrition Inst. v. Young*, 773 F.2d 1356 (D.C. Cir. 1985) . . . . . 6-7, 11

*Crestview Parke Care Center v. Thompson*, 373 F.3d 743 (6th Cir. 2004) . . . . . 18-19

*Hynson, Westcott & Dunning, Inc. v. Richardson*, 461 F.2d 215 (4th Cir. 1972) . . . . . 13

*National Corn Growers Ass'n. v. U.S. Environmental Protection Agency*, No. 10-1031, Petition for Writ of Certiorari (Feb. 16, 2011) . . . . . 4

*Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609 (1973) . . . . . 13-14 19

**Constitutions, Statutes, Regulations**

U.S. Const., Amend. V . . . . . 4

21 U.S.C. § 346(g) . . . . . 7

21 U.S.C. § 346a(g)(2)(B) . . . . . 8

40 C.F.R § 178.32(b) . . . . . 7, 12

**Miscellaneous**

Lemming, Theresa L., 73 Am Jur § 48 (2d ed. 2010) . . . . . 11

TABLE OF AUTHORITIES—Continued

Page

*Thomas, Prof. James C. The Fiftieth Anniversary of the Administrative Procedure Act: Past and Prologue: Fifty Years with the Administrative Procedure Act and Judicial Review Remains an Enigma,* 32 Tulsa. L.J. 259 (1996) . . . . . 17

## IDENTITY AND INTEREST OF AMICI CURIAE

Pursuant to Supreme Court Rule 37, Pacific Legal Foundation and the Cato Institute respectfully submit this brief amicus curiae in support of Petitioners, National Corn Growers Association, et al.[1]

Pacific Legal Foundation is the largest nonprofit, public interest organization of its kind in the country. Founded in 1973, the Foundation provides a voice in the courts for mainstream Americans who believe in limited government, private property rights, individual freedoms, and free enterprise. The Foundation litigates nationwide in state and federal courts with the support of thousands of citizens from coast to coast.

The Cato Institute was established in 1977 as a nonpartisan public policy research foundation dedicated to advancing the principles of individual liberty, free markets, and limited government. Cato's Center for Constitutional Studies was established in 1989 to help restore the principles of limited constitutional government that are the foundation of liberty. Toward those ends, Cato publishes books and studies, conducts conferences and forums, publishes

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[1] In accordance with Rule 37.3.(a), all parties have been timely informed of Amici's intent to participate in this case and have consented to the filing of this brief. Letters of consent have been filed with the Clerk of the Court.

Also, under Rule 37.6. Amici affirm that no counsel for any party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than Amici, their members, or their counsel have made a monetary contribution to the brief's preparation or submission.

the annual *Cato Supreme Court Review*, and files amicus briefs in pivotal cases.

In their efforts to protect fundamental constitutional rights, Pacific Legal Foundation and the Cato Institute become involved in cases that raise important public policy considerations that may create significant legal precedents.

This case is of vital concern to the public interest mission of Amici because the D.C. Circuit has established a rule of law effectively authorizing a nationwide ban on a necessary and effective product. Although the product has been safely used for more than four decades, neither the regulating agency nor the Court of Appeals will authorize an evidentiary hearing to resolve the agency's disputed claims that the product suddenly poses an unacceptable risk to the environment and human health. This case encourages government overreaching and establishes a dangerous precedent authorizing unilateral agency control of important markets and commodities with little or no process or meaningful judicial review.

## INTRODUCTION

Under the Federal Food, Drug, and Cosmetic Act (FFDCA), the Environmental Protection Agency establishes limits, or "tolerances," for pesticide residues on food. Joint Appendix at 2a (JA). A pesticide residue that exceeds an established tolerance is deemed "unsafe" and may not be moved in interstate commerce. *Id.* The product is effectively banned from use.

The EPA must modify or revoke a tolerance it deems unsafe through a notice and comment process. The EPA first issues a notice of proposed revocation and invites public comment on the proposal. *Id.* at 3a.

Then, the EPA issues a final rule either implementing or withdrawing the proposal. During this stage, any person may file an objection to the final rule. *Id.* Both the Act and the implementing regulations require the EPA to hold a public evidentiary hearing if the objections raise a "material issue of fact." *Id.*

Although Petitioners raised material issues of fact about the EPA's conclusions, the EPA revoked all tolerances for the pesticide carbofuran, without a public hearing.

There is a growing trend among federal agencies and the courts to expand the enforcement power of the government incrementally by adopting statutory interpretations that go beyond their plain meaning and intent. This case exemplifies government overreaching.

Contrary to common sense, clear language, and conflicting precedent, the D.C. Circuit held that a question of material fact as to the safety of a regulated product, that would normally trigger a statutory right to an evidentiary hearing, under the FFDCA, is nothing more than a "dispute between experts" and that the court will not substitute its judgment for that of the agency. This decision gives the EPA sole and complete discretion to determine which of thousands of products may be prohibited from use, without the benefit of a hearing, thereby depriving the public of arguably safe, effective, and even necessary products, and the manufacturers and suppliers of those products of their property and livelihood.

To be sure, summary judgment decisions ease the administrative burdens on regulatory agencies, like the EPA in this case, but at what cost? At the expense of

reliable decision making and fundamental fairness. The right to not be deprived of one's property without a fair process is a bedrock principle of American jurisprudence. *See* U.S. Const., Amend. V. It is a breach of the public trust when federal agencies fail to follow the very laws they are bound to enforce. And, when they are abetted by the courts, it serves only to undermine public confidence in government institutions.

To restore that confidence, this Court should review this case and reverse the decision below.

## STATEMENT OF THE CASE

Carbofuran was registered for use in 1969 by the EPA. For more than 40 years carbofuran has been safely used for pest control for a variety of crops, including corn, sunflowers, pumpkins, and potatoes. *National Corn Growers Ass'n. v. U.S. Environmental Protection Agency,* No. 10-1031, Petition for Writ of Certiorari at 7 (Feb. 16, 2011) (Pet.). During the 1980s, carbofuran was widely used on 35 domestic crops with an annual application rate of 10-11 million pounds a year. *Id.* Although its use is more limited today, carbofuran is still an indispensable product for some crops.

Like virtually any chemical, carbofuran can affect human health if exposure levels are high enough. However,"[t]here has never been a documented incident of any person suffering adverse health effects from dietary exposures to carbofuran, either from food or drinking water." Pet. at 7-8.

Nevertheless, in 2008-2009 the EPA determined that the pesticide posed an unacceptable risk to human health due to aggregate exposure in drinking water.

JA at 5a. This determination was based on a new worse case groundwater model and assumed the admittedly unlikely event "that 100% of crops that could be treated with carbofuran would be so treated." Pet. at 9.

To dispute the EPA's findings, Petitioners submitted extensive comments on the proposed revocation, including data that showed carbofuran did not exceed 4.25% usage in any watershed, let alone 100% as the EPA assumed. JA at 5a-6a. Petitioners also provided evidence that refuted the EPA's conclusions about the vulnerability of soils to leaching. *Id.* at 11a-13a. Moreover, Petitioners specifically raised four issues in objection to the final revocation:

> What are the concentrations of carbofuran in (1) surface water and (2) ground water; (3) what is the half-life of carbofuran, which is relevant in determining the extent to which an individual recovers between exposures; and (4) what is the 'safe dose' of carbofuran, "*i.e.*, the level below which exposures will not result in adverse effects."

JA at 5a-6a.

With respect to comments submitted on the proposed revocation, the EPA concluded the information was incomplete. With respect to comments submitted on the final rule, the EPA concluded the information was simply repetitive of the prior comments and did not consider it. Pet. at 26-29. Thus, in keeping with past practice, the EPA determined that these disputes did not rise to the level of a "material issue of fact" and denied Petitioners an evidentiary hearing. In the nearly forty years the EPA has been

required to hold a hearing of this type, it has never done so. *Id.* at 16.

On appeal, the D.C. Circuit adopted the view that "whether an issue is material differs from our review of a summary judgment rendered by a district court, which we review *de novo*." JA at 7a. Instead, the Circuit Court proclaimed the "proper standard of review here . . . is 'necessarily deferential.'" Citing its own prior ruling in *Community Nutrition Inst. v. Young*, 773 F.2d 1356, 1363 (D.C. Cir. 1985), the panel concluded:

> Mere differences in the weight or credence given to particular scientific studies, or in the numerical estimates of the average daily intake levels of [a substance], are insufficient. [We] will not substitute [our] judgment on highly technical and factual maters for that of the agency charged with the supervision of the industry.

*Id.*

On the issue of whether a hearing is required to resolve a material dispute, the court held: "[O]ur review 'is limited to an evaluation of whether [the agency] has given adequate consideration to all relevant evidence in the record.'" JA at 7a (citing *id.* at 1362). After acknowledging a legitimate dispute between EPA and Petitioners as to application rates and whether carbofuran will be applied to soils vulnerable to leaching into groundwater, the court concluded that such a "dispute between experts" was "fatal" to Petitioners' request for a hearing because, "[a]s we said in *Community Nutrition*, we will not overturn an agency's finding [that] there is no material

issue of fact based upon '[m]ere differences in the weight or credence given to particular scientific studies." JA at 13a (citing *Community Nutrition*, 173 F.2d at 1363).

## SUMMARY OF THE ARGUMENT

It does not overstate the case to say that the decision below gives the EPA *carte blanche* to determine the fate of literally thousands of products in the market. This case is not limited to carbofuran or pesticides alone. It sets a precedent for other products regulated under the Federal Food, Drug, and Cosmetic Act, including "prescription drugs, medical devices, agriculture, food products and additives, and many other consumer products." Pet. at 4. For this reason, review should be granted.

It is evident from the facts in this case, and the EPA's ongoing failure to ever hold a revocation hearing, that EPA has created a "no win" situation for Petitioners. Although the FFDCA and EPA regulations clearly require a public evidentiary hearing, *see* 21 U.S.C. § 346(g) and 40 C.F.R § 178.32(b), in a revocation proceeding, when material issues of fact are raised, the EPA invariably finds all contrary evidence insufficient for such a hearing. This is so unlikely as to defy belief, but the D.C. Circuit has refused to question EPA findings in such cases.

In effect, the court has written "material issue of fact" out of the Act. According to the D.C. Circuit, a disagreement over determinative facts, in a technical case, is nothing more than a "dispute among experts." Rather than embrace such a dispute as a classic issue of material fact, as commonly defined and as other courts have done, the court has declared that

differences in scientific studies and numerical estimates are simply "insufficient" for judicial review. Instead, the court held, it must defer to the agency, thereby, giving the EPA free rein to determine whether a product may move in interstate commerce.

Although the D.C. Circuit acknowledges that the FFDCA hearing requirement is based on a summary-judgment-type process, the court refused to apply a summary-judgment-type standard of review to its application, like it would in a district court case. But there is a greater need for searching appellate review of administrative summary decisions than judicial summary decisions because unlike a district court, the EPA is not a neutral arbiter of the facts. To the contrary, the agency' objectivity is compromised because it must defend itself against Petitioners' objections.

## ARGUMENT

The D.C. Circuit's holding that a "dispute between experts" is fatal to a request for an evidentiary hearing under the FFDCA undermines the Act, nullifies legal safeguards, and is contrary to summary-judgment-type proceedings.

### A. Review Is Warranted Because the Lower Court Undermined the Legal Requirement for a Hearing Under the FFDCA

It is undisputed that the FFDCA requires the EPA to convene a public hearing if such a "hearing is necessary **to receive factual evidence** relevant to material issues of fact" raised by objectors. 21 U.S.C. § 346a(g)(2)(B) (emphasis added). But the D.C. Circuit, the primary arbiter of administrative rules, has

twisted this clear and unambiguous language beyond all reason.

According to the D.C. Circuit, its review as to whether a hearing is properly denied "'is limited to an evaluation of whether the agency has given adequate consideration to all relevant evidence in the record.'" JA at 7a. This standard flatly and illegally contradicts the statutory language which expressly states that the purpose of a hearing is to "receive factual evidence" related to the material issue of fact. *See Chevron v. Natural Resources Defense Council*, 467 U.S. 837, 842-43 (1984) (If Congress has expressly spoken to the precise question at issue, then that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.).

The law cannot be read both ways. Either the EPA must determine whether a hearing is required before receiving all the factual evidence relevant to a material issue of fact, as the court has authorized, or it must hold a hearing to receive the evidence of a material issue of fact the EPA is on notice exists, as the plain language of the Act suggests. Two examples illustrate the problem with the court's interpretation.

First, during the administrative proceedings, Petitioners challenged the EPA's assumption that carbofuran would be applied in 100% of the areas in which it was legally allowed by providing data that showed a more realistic application rate of 4.25%. JA at 10a. Although the EPA agreed that "'it is unlikely that 100% of the crop will be treated . . . in most watersheds,'" the agency refused to grant Petitioners a hearing on this issue arguing that Petitioners had

failed to "submit much of the data and the methodology they used" to arrive at their estimate. *Id.*

Second, and likewise, Petitioners challenged the EPA's conclusion that concentrations of carbofuran in groundwater exceeded safe levels. *Id.* at 11a-12a. In their comments on the proposed revocation, Petitioners relied on a "National Leaching Assessment" conducted by "independent water experts" that demonstrated that carbofuran would not be used in areas with high leaching vulnerability. *Id.* at 12a. But as with the other issue, the EPA claimed that Petitioners did not submit the Assessment itself at the comment stage or "explain sufficiently the data and methodologies underlying it." *Id.* It made no difference that additional data was provided at the objection stage of the proceedings. The EPA denied Petitioners' request for a hearing. *Id.*

In recounting these incidents, the court did not question that these disputes raised material issues of fact. To the contrary, the court conceded the point: "The petitioners' challenges to the EPA's conclusion that concentrations exceed safe levels turns, the parties agree, upon a single issue of fact, *viz.*, whether carbofuran will be applied in the areas with soil that is 'vulnerable' to the carbofuran leaching into the groundwater." *Id.* at 11a-12a. But the court ignored this observation and deferred entirely to the judgment of the EPA that a hearing was not required to resolve a clearly determinative dispute.

Under the court's deference standard and EPA practice, therefore, no one could ever obtain a public hearing. Either Petitioners would never satisfy the informational demands of the EPA to warrant a hearing or the EPA would conclude the evidence it was

provided was insufficient to change the outcome of the revocation order and a hearing is unnecessary. This "catch-22" makes a mockery of the Act and no doubt accounts for the implausible fact that the EPA has never held a public hearing on a revocation rule in the nearly 40 years the hearing requirement has existed.

### B. Review Is Warranted To Establish the Proper Standard of Review Under the FFDCA for a Public Hearing

By deferring to the judgment of the EPA on the need for a hearing, the court has effectively written "material issue of fact" out of the Act. According to the court below, a "material issue of fact" must be something other than a "dispute among experts." "Mere differences in weight or credence given to particular scientific studies, or in the numerical estimates of the average daily intake of [a substance], are insufficient." JA at 7a (citing *Community Nutrition*, 773 F.2d at 1363).

But why is this so? In a technical case an argument about a "material issue of fact" will almost always be a "dispute among experts."

It is axiomatic that a difference in numerical estimates as to the rate of pesticide application within a watershed, or the porosity of the soils, or the quantitative impact on groundwater, or the dose and half-life of a toxic substance, or the weight and credence of scientific studies each can change the outcome of a health assessment as the EPA undertook in this case for carbofuran. This is the very essence of a "material issue of fact" as commonly understood. *See* Theresa L. Lemming, 73 Am Jur § 48 (2d ed. 2010) ("material" means that the contested fact has the

potential to alter the outcome of the dispute and "material facts" are those that tend to prove or disprove an element of a disputed claim).

This common understanding of the term "material issue of fact" was adopted in greater detail in the EPA's own implementing regulations which both the EPA and the court acknowledged but did not follow:

> A request for an evidentiary hearing will be granted if the Administrator determines that the material submitted shows the following:
>
> (1) There is genuine and substantial issue of fact for resolution at a hearing. An evidentiary hearing will not be granted on issues of policy or law.
>
> (2) There is a reasonable possibility that available evidence identified by the requester would, if established, resolve one or more of such issues in favor of the requestor . . . . An evidentiary hearing will not be granted . . . if the Administrator concludes that the data and information submitted, even if accurate, would be insufficient to justify the factual determination urged.
>
> (3) Resolution of the factual issue(s) in the manner sought . . . would be adequate to justify the action requested. An evidentiary hearing will not be granted on factual issues that are not determinative with respect to the action requested.

40 C.F.R. § 178.32(b).

The Circuit Court provided no analysis whatsoever of these hearing factors. To the contrary, the court simply reiterated the EPA's conclusions and upheld the hearing denial. The issues of fact raised by Petitioners with respect to pesticide application rates, vulnerable soils, and contested EPA assumptions are clearly not issues of policy or law under factor (1). Had the EPA considered the data and methodologies on which Petitioners relied (but were denied for lack of a hearing) there is a reasonable possibility that the evidence would have established the fact in Petitioners' favor under factor (2). And were the Petitioners' correct about the facts asserted, they would have justified a different outcome as Petitioners requested under factor (3). EPA's self-serving and predetermined conclusions to the contrary do not satisfy these statutory or regulatory standards.

More to the point, this Court has never held that a "dispute between experts" is fatal to a request for an evidentiary hearing while other Circuits have concluded that such a dispute is a quintessential material issue of fact. *See* Pet. at 23-26, 30-31 (for discussion of circuit splits). In *Hynson, Westcott & Dunning, Inc. v. Richardson*, 461 F.2d 215 (4th Cir. 1972), affirmed in relevant part by this Court in *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609 (1973), and discussed in detail throughout the Petition for Certiorari in this case, the Fourth Circuit considered whether an evidentiary hearing was required under the FFDCA given a dispute among the experts about the safety of a drug that was proposed for withdrawal. In that case, the agency claimed there was no substantial issue as to material fact on the same basis the EPA asserted in this case; that the technical studies on which petitioners relied did not

disclose their complete data or methodologies. *Hyson*, 461 F.2d at 221. The Fourth Circuit held, however, that the hearing was required before withdrawing the drug precisely because of a dispute between experts. *Id.* Relying on both constitutional and statutory principles, the court determined that neither due process nor the Administrative Procedure Act permitted an arbitrary denial of a request for a hearing in a case where it can be fairly said there are genuine and substantial issues of fact in dispute. *Id.*

### C. Review Is Warranted To Curtail Abuse of the Administrative Process

The D.C. Circuit acknowledged that the parties agreed the FFDCA and the EPA's regulations establish a "summary-judgment-type" standard for determining whether to hold an evidentiary hearing. JA at 6a. But this is a small concession as both the Act and the regulations require a hearing when material issues of fact are raised. Nevertheless, the court held that its "review of the EPA's exercise of discretion in determining whether an issue is material differs from our review of a summary judgment rendered by a district court, which we review *de novo*." *Id.* at 6a-7a. Rather, the court concluded its review is limited to an evaluation of whether the agency adequately considered the record. *Id.* at 7a.

The court provided no principled justification for this difference. Nor can it. Greater safeguards are needed to protect Petitioners in the administrative process than in the judicial process. Among other things, summary judgment in the district court at least involves a neutral arbiter. This is certainly not true in an administrative setting where the agency is

defending itself. Therefore, the agency has an inherent bias.

This bias was on ready display in this case when the EPA discounted any evidence Petitioners submitted as incomplete, redundant, or unreliable and doggedly held to its revocation ruling with self-serving rationalizations. *See* Pet. at 11 n.3 ("EPA's order is replete with such analysis."). In one outrageous example, the EPA revoked import tolerances for carbofuran even though the EPA acknowledged exposure to the pesticide from imported foods was safe. JA at 14a. The justification the agency offered in support of this nonsensical ruling was twofold: (1) that the Petitioners' request to leave the import tolerances in effect was untimely and (2) that the Petitioner's request to leave the import tolerances in effect was argued in the alternative and was, therefore, invalid. *Id.*

As to the first justification, the court held it was "untenable" because Petitioners had timely made the request on at least two occasions. As to the second justification—the argument in the alternative—the court stated bluntly: "That is a strange idea, rejection of which requires no display of learning." *Id.* In the end, the court determined that EPA's revocation of the import tolerance was arbitrary and capricious under the Administrative Procedure Act and reversed that part of the EPA's ruling. *Id.*

But there were other examples of blatant bias the court left intact. As with the import tolerances, the EPA denied Petitioners a hearing claiming their detailed arguments about the concentration of carbofuran in groundwater and surface water were untimely although these arguments were properly raised at both the comment and objection stages. *See*

Pet. at 9-10. And, beyond all reason, the EPA claimed it was compelled to assume that carbofuran would be applied to its full legal extent—to 100% of authorized crop use—when Petitioners provided evidence that this was an unreasonable assumption and the product was typically used only on 4.25% of crops for which it was authorized. JA at 5a-6a.

Unfortunately, this cavalier treatment of the evidence is not just an isolated event. The undisputed fact that the EPA has never held an evidentiary hearing of this type should give pause to the most devout agency apologist. The EPA has openly expressed its disfavor of the hearing requirement, if such was not evident from the agency's actions. According to the EPA, FFDCA hearings are "time-consuming" and "unnecessary." Pet. at 16. Such hearings may be time-consuming, but they are required by law. The necessity of such hearings to contest EPA's entrenched positions should now be self-evident. Such hearings are required for the obvious purpose of providing a fair process to Petitioners before depriving them and the public of a valuable commodity.

Carbofuran has "few, if any effective alternatives." *Id.* at 8. Therefore, the economic impact of banning the product is substantial. "Banning carbofuran is estimated to cost growers, applicators, vendors, and the downstream farm economies $86-254 million from the loss of carbofuran on corn, $56-190 million from its loss on potatoes, and $13-22 million from its loss on sunflowers." *Id.* at 8. But this is only one example of many thousands of products subject to regulation under the FFDCA.

In addition to the FFDCA hearing requirement, the Administrative Procedure Act (under which this

case was brought) was promulgated to protect the public from agency abuse of the kind revealed in this case.

> Within the expanding administrative state, the people are left with no choice but to rely on the protection offered by a reviewing court. For with the delegation of legislative power to administrative agencies, the people's political protection against legislative abuse is made less effective.

Prof. James C. Thomas. *The Fiftieth Anniversary of the Administrative Procedure Act: Past and Prologue: Fifty Years with the Administrative Procedure Act and Judicial Review Remains an Enigma*, 32 Tulsa. L.J. 259, 284 (1996).

Thus,

> [t]he role of the courts in the new Administrative Procedure Act was well defined in both the House and Senate Committee Reports. With respect to Congress' intent for "scope of review," each report stated in identical language: "*Reviewing courts are required to decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of agency action.*"

*Id.* (emphasis added).

### D. Review Is Warranted To Establish That Complete Deference Is Not Compatible with a Summary-Judgment-Type Proceeding

Because the FFDCA provides for a summary-judgment-type hearing requirement, the D.C. Circuit should have applied a summary-judgment-type review as this and other courts have done. In *Crestview Parke Care Center v. Thompson*, 373 F.3d 743 (6th Cir. 2004), the Circuit Court was called on to determine if the Care Center was properly denied a hearing in an administrative summary judgment process analogous to the FFDCA. The court ruled that the imposition of an administrative penalty without an agency hearing was a misapplication of the summary judgment standard. *Id.* at 755. The court explained that in evaluating whether summary judgment is proper, it does not weigh the evidence but it does review the evidence in the light "most favorable" to the petitioner, *id.* – which neither the EPA nor the D.C. Circuit did in this case.

The Sixth Circuit went on to explain that it was improper for the agency to compare the relative strength of the evidence adduced by the agency and the petitioner without a hearing because when both sides offer differing arguments about the underlying question, "this is a factual dispute at its essence." *Id.* "This factual dispute makes the cancellation of an in-person hearing improper." *Id.* at 755-56. But the court in this case came to the opposite conclusion. So long as the EPA claimed there was no "factual dispute at its essence," the D.C. Circuit would defer to the agency judgment.

Finally, the court in *Crestview* observed that if a hearing was held, on remand, the agency would not be obligated to rule in favor of the petitioner.

> Upon remand, the ALJ may conclude in fact that Crestview has not proven it acted reasonably in failing to adhere to these residents' plans of care. Nonetheless, taking the evidence in the light most favorable to Crestview, a genuine dispute of material fact exists regarding the violation of § 483.25. Summary judgment without an in-person hearing on the issue of the asserted violations involving these two residents was thus improper.

*Id.* at 754.

Similarly, in *Weinberger*, this Court explained the contours of a summary-judgment-type process under the FFDCA. Of primary concern is this Court's directive that a reviewing court must assure itself that the agency's "findings accurately reflect the study in question and if they do, whether the deficiencies [found] conclusively . . . render the study inadequate" to warrant a hearing. 412 U.S. at 622. But this approach cannot be reconciled with the absolute deference the D.C. Circuit gave the EPA in its evaluation of the studies relied on by Petitioners in this case.

To the contrary, this is the very type of review the court below held it could not provide:

> Mere differences in weight or credence given to particular scientific studies, or in the numerical estimates of the average daily intake of [a substance], are insufficient. [We]

> will not substitute [our] judgment on highly technical and factual maters for that of the agency charged with the supervision of the industry.

JA at 7a.

## CONCLUSION

The D.C. Circuit has held that the EPA's hearing decisions under the FFDCA must be given absolute deference so that the court does not substitute its judgment for that of the agency. This decision establishes a far-reaching precedent in conflict with the language of the Act, the intent of Congress, and the precedent established by this and other courts that have considered summary-judgment-type agency decisions. Moreover, it institutionalizes administrative abuses the APA and other laws (including the FFDCA) were designed to prevent.

Accordingly, this Court should grant the petition to review that decision.

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Respectfully submitted,

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